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23 IN THE UNITED STATES DISTRICT COURT

24 FOR THE CENTRAL DISTRICT OF CALIFORNIA

25 WESTERN DIVISION

26 UNITED STATES OF AMERICA;
27 the STATES of CALIFORNIA,
28 DELAWARE, FLORIDA,
29 GEORGIA, HAWAII, ILLINOIS,
30 INDIANA, LOUISIANA,
31 MICHIGAN, MINNESOTA,
32 MONTANA, NEVADA, NEW
33 HAMPSHIRE, NEW JERSEY, NEW
34 MEXICO, NEW YORK, NORTH
35 CAROLINA, OKLAHOMA, RHODE
36 ISLAND, TENNESSEE, TEXAS, and
37 WASHINGTON;
38 COMMONWEALTHS of

No. CV 13-5861 JLS (AJWx)

INTERVENING STATES'
CONSOLIDATED COMPLAINT IN
INTERVENTION

JURY DEMAND

1 MASSACHUSETTS and VIRGINIA,
2 and the DISTRICT OF COLUMBIA
ex rel. MARIA GUZMAN,

3 Plaintiffs,

4 v.

5 INSYS THERAPEUTICS, INC.;
6 MICHAEL BABICH, an individual;
7 ALEC BURLAKOFF, an individual;
8 JOHN N. KAPOOR, and DOES 2
through 15,

Defendants.

9 UNITED STATES OF AMERICA *ex*
10 *rel.* JANE DOE and the States of
11 CALIFORNIA, COLORADO,
12 CONNECTICUT, DELAWARE,
13 FLORIDA, GEORGIA, HAWAII,
14 ILLINOIS, INDIANA, IOWA,
15 LOUISIANA, MARYLAND,
16 MASSACHUSETTS, MICHIGAN,
17 MINNESOTA, MONTANA,
18 NEVADA, NEW JERSEY, NEW
19 MEXICO, NEW YORK, NORTH
20 CAROLINA, OKLAHOMA,
21 RHODE ISLAND, TENNESSEE,
22 TEXAS, VERMONT, VIRGINIA,
WASHINGTON, the CITY OF
CHICAGO, and the DISTRICT OF
COLUMBIA,

Plaintiffs,

v.

INSYS THERAPEUTICS, INC. and
LINDEN CARE LLC,

Defendants.

No. CV 16-7937 JLS (AJWx)

COMPLAINT IN INTERVENTION OF THE INTERVENING STATES

I. INTRODUCTION

1. This is a civil action brought by the states of California, Colorado, Indiana, Minnesota, New York, North Carolina, and Virginia (hereinafter jointly referred to as “the Intervening States”) to recover treble damages and civil penalties under their respective state false claims acts, other state statutes, and the common law.

2. Fentanyl is a powerful, but highly addictive, opioid painkiller. Defendant Insys Therapeutics, Inc. (“Insys”) is the manufacturer of Subsys, a sublingual spray form of fentanyl. In 2012, Subsys was approved by the U.S. Food and Drug Administration (“FDA”) for the treatment of breakthrough pain in adult cancer patients who are already receiving, and tolerant to, around-the-clock opioid therapy for underlying persistent cancer pain.

3. Beginning in or about May 2012 and continuing until the present, Insys has knowingly offered and paid kickbacks to induce physicians, physician assistants, nurse practitioners, and other providers to prescribe Subsys for their patients. The kickbacks include, but are not limited to, payments to physicians for sham speaker programs and providing lavish meals and entertainment.

4. Insys knowingly caused the Medicaid programs of the Intervening States to pay for Subsys for unapproved uses. Insys did this by, among other things,

1 (1) encouraging prescribers to prescribe Subsys in situations where it was not
2 medically reasonable and necessary based on patients' medical conditions (i.e.,
3 because a patient did not have cancer), and (2) misrepresenting patients' medical
4 diagnoses to the Intervening States' Medicaid Programs or their Pharmacy Benefits
5 Managers in order to obtain reimbursement for Subsys.
6

7
8 5. Insys's conduct violates the federal Anti-Kickback Statute ("AKS"), 42
9 U.S.C. § 1320(a)-7b, the federal False Claims Act ("FCA"), 31 U.S.C. §§ 3729-
10 3733, the respective state false claims acts of the Intervening States, and other state
11 statutes. The Intervening States and the United States, through its joint contributions
12 to the Medicaid Programs of the Intervening States, have suffered tens of millions
13 of dollars in damages due to Insys's misconduct.
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15 II. JURISDICTION AND VENUE

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17 6. In August 2013, Relator Maria Guzman filed the first of the five (5)
18 consolidated actions against Insys, *United States ex rel. Guzman v. Insys*
19 *Therapeutics, Inc.*, 13-cv-5861 JLS (AJWx) (C.D. Cal.), pursuant to the *qui tam*
20 provisions of the FCA, 31 U.S.C. § 3730(b). In November 2015, Guzman filed her
21 First Amended Complaint, which added claims on behalf of twenty-five (25) states,¹
22 including every intervening state but Colorado, pursuant to the respective state false
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26
27 ¹ The term "states" includes the fifty (50) states, however denominated, and the District of
28 Columbia. This definition is in accord with the definition of state found at 42 U.S.C. § 1301(a).

1 claims acts. In June 2016, Guzman filed her Second Amended Complaint, which
2 again included claims on behalf of the same twenty-five (25) states.

3
4 7. In October 2016, Relator Melina Spalter filed the fifth² of the
5 consolidated actions, *United States ex rel. Doe v. Insys Therapeutics, Inc.*, 16-cv-
6 7937 JLS (AJWx) (C.D. Cal.) pursuant to the *qui tam* provisions of the FCA, 31
7 U.S.C. § 3730(b) and the respective state false claims acts of the twenty-nine (29)
8 named states, including the Intervening States.

9
10 8. On April 25, 2018, the states of California, Colorado, Indiana, New
11 York, North Carolina, and Virginia filed a joint notice of their intent to partially
12 intervene pursuant to their respective state false claims acts. On June 27, 2018,
13 Minnesota filed its notice of intent to partially intervene. On July 20, 2018, the Court
14 granted the Intervening States (including Minnesota) until August 9, 2018 to file
15 their Consolidated Complaint in Intervention.

16
17 9. This Court has subject matter jurisdiction over this action pursuant to
18 28 U.S.C. §§ 1331 and 1345, and pursuant to 31 U.S.C. § 3732(b) because the action
19 arises from the same transaction or occurrence as an action brought under 31 U.S.C.
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26 ² The Relators in the second, third, and fourth cases, respectively, *United States ex rel. Andersson*
27 *v. Insys Therapeutics, Inc.*, CV 14-9179 JLS (AJWx), *United States ex rel. Doe v. Insys*
28 *Therapeutics, Inc.*, CV 14-3488 JLS (AJWx), and *United States ex rel. Erickson v. Insys*
Therapeutics, Inc., CV 16-2956 JLS (AJWx), did not make claims on behalf of the states.

1 § 3730. Additionally, the Court has supplemental jurisdiction over the state
2 statutory, common, and equitable causes of action pursuant to 28 U.S.C. § 1367(a).

3
4 10. Venue lies in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.
5 C. §§ 1391 (b) and 1391(c) because Insys does business in this District and some of
6 the false or fraudulent acts committed by Insys occurred in this District.

7
8 III. PARTIES

9 11. Plaintiff the State of California was and is at all relevant times to this
10 action a sovereign state of the United States of America.

11
12 12. Plaintiff the State of Colorado was and is at all relevant times to this
13 action a sovereign state of the United States of America.

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15 13. Plaintiff the State of Indiana was and is at all relevant times to this
16 action a sovereign state of the United States of America.

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18 14. Plaintiff the State of Minnesota was and is at all relevant times to this
19 action a sovereign state of the United States of America.

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21 15. Plaintiff the State of New York was and is at all relevant times to this
22 action a sovereign state of the United States of America.

23
24 16. Plaintiff the State of North Carolina was and is at all relevant times to
25 this action a sovereign state of the United States of America.

1 17. Plaintiff the Commonwealth of Virginia was and is at all relevant times
2 to this action a sovereign state of the United States of America.³

3 18. At the time of filing her original complaint, Relator Maria Guzman was
4 a resident of Virginia and a former Insys employee.

5 19. At the time of filing her original complaint, Relator Melina Spalter was
6 a resident of New Jersey and a former Insys employee.

7 20. Defendant Insys is a pharmaceutical manufacturer that is incorporated
8 in Delaware, and is headquartered at 1333 South Spectrum Boulevard, Suite 100, in
9 Chandler, Arizona.

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13 **IV. THE MEDICAID PROGRAM**

14 21. Medicaid is a cooperative federal-state program that provides health
15 care benefits, including, but not limited to, prescription drug coverage, to qualified
16 groups such as the elderly, impoverished or disabled. The federal government offers
17 funding to state Medicaid programs provided they meet certain minimum
18 requirements as set forth under the federal Medicaid statute, 42 U.S.C. § 1396a. The
19 amount of federal funding afforded to each state's Medicaid program, otherwise
20 known as the Federal Medical Assistance Percentage ("FMAP"), is based on each
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³ The Virginia Office of the Attorney General brings this action in the name of the Commonwealth
26 of Virginia exclusively on behalf of and for damages incurred by the Commonwealth through the
27 Virginia Department of Medical Assistance Services ("DMAS"), the single state agency
28 designated to administer the Medicaid program in Virginia under Title XIX of the Social Security
Act.

1 state's per capita income compared to the national average. *Id.* § 1396d(b). Each
2 state pays the remaining balance that the FMAP funds do not cover out of the state's
3 budget ("State Share").
4

5 22. Reimbursement for prescription drugs under the Medicaid program is
6 available for "covered outpatient drugs." 42 U.S.C. §§ 1396b(i)(10), 1396r-8(k)(2)
7 and (3). Covered outpatient drugs are those which are used for a "medically accepted
8 indication." *Id.* § 1396r-8(k)(3). A medically accepted indication is one that has
9 been approved by the FDA. *Id.* § 1396r-8(k)(6). Subsys is FDA approved for a
10 limited indication – the management of breakthrough pain in cancer patients
11 eighteen (18) years of age and older who are already receiving and who are tolerant
12 to opioid therapy for their underlying persistent cancer pain. Further, Subsys may
13 be dispensed only to patients enrolled in the Transmucosal Immediate Release
14 Fentanyl ("TIRF") Risk Evaluation and Mitigation Strategy ("REMS") Access
15 program.
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20 23. Additionally, the Intervening States may require, as a condition of
21 coverage or payment for certain covered outpatient drugs, the approval of the drug
22 before it is dispensed for any medically accepted indication. *See* 42 U.S.C. § 1396r-
23 8(d)(1) (Permissible Restrictions) and 42 U.S.C. § 1396r-8(d)(5) (Prior
24 Authorizations).
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V. APPLICABLE LAW

A. The State False Claims Acts

24. Each of the Intervening States has its own state false claims act that imposes liability for, among other things, knowingly submitting, or causing to be submitted, false or fraudulent claims to the States' Medicaid programs, and for knowingly making, using, or causing to be made or used, false records or statements material to false or fraudulent claims made to the States' Medicaid programs. *See* Cal. Gov't Code § 12650 *et seq.*; Col. Rev. Stat. Ann. § 25.5-4-303.5 *et seq.*; Ind. Code Ann. § 5-11-5.5 *et seq.*;⁴ Minn. Stat. Ann. § 15C.01 *et seq.*; N.Y. State Fin. Law § 187 *et seq.*; N.C. Gen. Stat. Ann. § 1-605 *et seq.*; Va. Code Ann. § 8.01-216.1 *et seq.* These statutes are analogous to the FCA, 31 U.S.C. § 3729 *et seq.*

B. The Federal Anti-Kickback Statute and State Prohibitions on Kickbacks

25. The AKS arose out of congressional concern that remuneration given to those who can influence health care decisions would result in the provision of

⁴Actions related to false claims presented to the Indiana Medicaid program from July 1, 2005 through June 30, 2014 could be brought under the Indiana False Claims and Whistleblower Protection Act, Ind. Code Ann. § 5-11-5.5 *et seq.* ("the Indiana FCA"). On July 1, 2013, the Indiana Medicaid False Claims and Whistleblower Protection Act, Ind. Code Ann. § 5-11-5.7 *et seq.* ("the Indiana FCA"), was enacted and actions related to false claims presented to the Indiana Medicaid program after that date could be brought under either the Indiana FCA or the Indiana MFCA. On July 1, 2014, both statutes were amended so that actions related to false claims presented to the Indiana Medicaid program after that date could only be brought under the Indiana MFCA.

1 goods and services that are medically unnecessary, of poor quality, or even harmful
2 to a vulnerable patient population. To protect patients and federal healthcare
3 programs, including Medicare and Medicaid, from these harms, Congress enacted a
4 prohibition against the payment of kickbacks in any form. First enacted in 1972,
5 Congress strengthened the AKS in 1977 and 1987 to ensure that kickbacks
6 masquerading as legitimate transactions did not evade its reach. *See* Social Security
7 Amendments of 1972, Publ. L. No. 92- 603, § 242(b) and (c), 86 Stat. 1329 (1972)
8 (codified at 42 U.S.C. § 1320a-7b); Medicare-Medicaid Anti-Fraud and Abuse
9 Amendments, Pub. L. No. 95-142, 91 Stat. 1175 (1977); Medicare and Medicaid
10 Patient Program Protection Act of 1987, Pub. L. No. 100-93, 101 Stat. 680 (1987).

14 26. The AKS makes it illegal for individuals or entities to “offer[] or pay[]
15 any remuneration (including any kickback, bribe, or rebate) ... to any person to
16 induce such person ... to purchase, ... order, ... or recommend purchasing ... or
17 ordering any good ... or item for which payment may be made in whole or in part
18 under a Federal health care program.” 42 U.S.C. § 1320a-7b(b)(2). Payments by a
19 pharmaceutical company to providers to induce them to prescribe the company’s
20 drugs violate this statute to the extent that the drugs are reimbursed by a federal
21 health care program.

25 27. The Patient Protection and Affordable Care Act of 2010 (“PPACA”),
26 Pub. L. No. 111-148, § 6402(f), 124 Stat. 119 (codified at 42 U.S.C. § 1320a-7b(g)),
27

1 amended the AKS to provide that “a claim that includes items or services resulting
2 from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of
3 [the FCA].”
4

5 28. The United States paid a portion of every Medicaid dollar expended by
6 the Intervening States for Subsys prescriptions. The United States would not have
7 paid their portion of the Medicaid claims for Subsys prescriptions if the government
8 knew the prescriptions were written in violation of the AKS. The Medicaid
9 Programs for the Intervening States would not have paid their state-share of the
10 Medicaid dollars expended for these prescriptions if the Programs had known that
11 the United States would not have paid their share of the claims. As a result, every
12 Subsys prescription that resulted from a violation of the AKS is automatically a false
13 claim under the Intervening States’ false claims act statutes.
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17 29. The Intervening States have a variety of state statutes, regulations or
18 requirements that allow them to recover monies their Medicaid programs paid for
19 goods or services that were tainted by kickbacks.
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21 30. Compliance with these state statutes, regulations, or requirements are
22 conditions of payment under the Medicaid programs of the Intervening States, and
23 the Intervening States will not pay for Medicaid claims tainted by kickbacks. *See*
24 *e.g.*, Ind. Code § 12-15-24-1; N.C.G.S. § 108A-63(g)-(h); and Va. Code Ann. § 32.1-
25 315.
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1 VI. SUBSYS

2 A. FDA Regulations and the Food, Drug, and Cosmetics Act

3 31. The Food, Drug, and Cosmetics Act (“FDCA”), 21 U.S.C. § 301 *et seq.*,
4 requires that drug manufacturers obtain approval from the FDA prior to marketing
5 and selling a new drug in the United States. Relevant here, drug manufacturers must
6 submit a “new drug application” (“NDA”) to the FDA to demonstrate the safety and
7 effectiveness of a new drug for its intended use(s). *Id.* § 355(a), (d). NDAs must
8 include, among other things, “full reports of investigations which have been made
9 to show whether or not such drug is safe for use and whether or not such drug is
10 effective in use,” *Id.* § 355(b)(1)(A), and “specimens of the labeling proposed to be
11 used for such drug.” *Id.* § 355(b)(1)(F).
12

13 32. The indication and dosages that have been approved by the FDA are
14 included in the drug’s labeling, and the content of the drug’s labeling must also be
15 approved by the FDA. 21 U.S.C. §§ 352, 355. The FDA will not approve a NDA
16 if, among other things, the drug’s investigations do not demonstrate that the drug is
17 safe for use as suggested in the proposed labeling, the drug has not been
18 demonstrated to have the effect suggested in the proposed labeling, or the proposed
19 labeling is false or misleading. *Id.* § 355(d). The label must include a variety of
20 information, including indications, dosage and administration, adverse reactions,
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1 contraindications, interactions, and use by specific patient populations. 21 C.F.R. §
2 201.57.

3 33. The FDCA prohibits manufacturers from introducing “misbranded”
4 drugs into interstate commerce. 21 U.S.C. § 331(a). A drug is “misbranded” if,
5 among other things, its labeling does not include “adequate directions for use,” *Id.* §
6 352(f)(1), or “directions under which the layman can use a drug safely and for the
7 purposes for which it is intended.” 21 C.F.R. § 201.5. In turn, “intended uses”
8 includes all uses objectively intended by the manufacturer, as demonstrated by
9 labeling, advertisements, oral or written statements, or circumstances suggesting that
10 the drug was knowingly “offered and used for a purpose for which it is neither
11 labeled nor advertised.” *Id.* § 201.128. Similarly, the FDA prohibits drug
12 manufacturers from utilizing marketing and promotional materials that are false or
13 misleading. 21 U.S.C. §§ 331, 352; 21 C.F.R. § 314.81.

14 34. The FDA may also require a drug manufacturer to implement a REMS
15 if the FDA determines that it “is necessary to ensure that the benefits of the drug
16 outweigh the risks....” 21 U.S.C. § 355-1(a)(1). In some instances, drugs may be
17 deemed to have “inherent toxicity or potential harmfulness” and be “associated with
18 a serious adverse drug experience.” *Id.* § 355-1(f)(1). Because of the increased risks
19 associated with the drug, the FDA may require that “health care providers who
20 prescribe the drug have particular training or experience,” that “each patient using
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1 the drug be subject to certain monitoring,” or that “each patient using the drug be
2 enrolled in a registry.” *Id.* § 355-1(f)(3).

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4 35. On or about December 28, 2011, the FDA originally approved a shared
5 REMS system applicable to all so-called TIRF medicines. According to the FDA,
6 the “goals of the TIRF REMS Access program are to mitigate the risk of misuse,
7 abuse, addiction, overdose and serious complications,” including ensuring the
8 “[p]rescribing and dispensing [of] TIRF medicines only to appropriate patients....”⁵
9
10 To prescribe TIRF medicines, providers must enroll in the TIRF REMS Access
11 program and certify, among other things, that they “understand that TIRF medicines
12 are indicated only for the management of breakthrough pain in cancer patients,” that
13 “TIRF medicines must not be used to treat acute or postoperative pain,” and “that
14 the initial starting dose for TIRF medicines for all patients is the lowest dose....”⁶
15
16 Patients, pharmacies, and distributors that are receiving, dispensing, and distributing
17 TIRF medicines must likewise enroll in the TIRF REMS Access program and make
18 similar certifications related to the approved uses for TIRF medicines and the
19 associated risks.⁷
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25 ⁵ Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy
26 (REMS), at 2, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/remis/TIRF_2017-09-07_Full.pdf

27 ⁶ *Id.* at 3.

28 ⁷ *See id.*

1 B. FDA Approval of SUBSYS

2 36. On or about January 4, 2012, the FDA approved Insys's NDA for
3 Subsys and added it to the TIRF REMS Access program. In its approval letter, the
4 FDA noted that "a REMS is necessary for Subsys (fentanyl sublingual spray) to
5 ensure the benefits of the drug outweigh the risks of misuse, abuse, addiction,
6 overdose, and serious complications due to medication errors."⁸ As one element of
7 the REMS for Subsys, the FDA required "the distribution of a Medication Guide"
8 because it was determined to be "necessary for patients' safe and effective use of
9 Subsys...."⁹ The FDA further noted that Subsys "is a product for which patient
10 labeling could help prevent serious adverse effects and that has serious risks (relative
11 to benefits) of which patients should be made aware...."¹⁰

12 37. At the time of Subsys's initial approval, the FDA-approved dosing
13 language, which remained until in or about July of 2013, included a statement that
14 for all patients, "[t]he initial dose of SUBSYS to treat episodes of breakthrough
15 cancer pain is **always** 100 mcg."¹¹ In or about July of 2013, the dosing language for
16 Subsys was revised to state that "[t]he initial dose of SUBSYS is always 100 mcg
17 with the only exception of patients already using Actiq."¹² Actiq is a fentanyl oral
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25 ⁸ https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202788Orig1s000Approv.pdf

26 ⁹ *Id.*

27 ¹⁰ *Id.*

28 ¹¹ https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202788s000lbl.pdf

¹² https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/202788s005s006lbl.pdf

1 transmucosal lozenge for breakthrough cancer pain, and the revised Subsys labeling
2 went on to include a conversion chart for patients being converted from Actiq to
3 Subsys. The original label for Subsys also explicitly provided that “SUBSYS is
4 indicated for the management of breakthrough pain in adult cancer patients” who are
5 “considered opioid tolerant.” Language to this effect has always been present in
6 Subsys’s labeling, and at all relevant times, Subsys is and has been FDA approved
7 only for the management of breakthrough cancer pain in opioid-tolerant patients.
8

9 VII. INSYS’S MISCONDUCT

10 C. Insys Paid Kickbacks to Potential Prescribers to Induce Them to 11 Prescribe Subsys

12 38. Since 2012, Insys has operated the Insys Speaker Program (sometimes
13 referred to as the “ISP”) through which it paid speaker fees to doctors and other
14 health care professionals to give presentations about Subsys. These speaker
15 programs were, in fact, a pretext for paying thousands of dollars and providing
16 expensive meals and other inducements to the “speakers” and attendees to induce
17 the speakers and attendees to prescribe Subsys. Many speaker programs were
18 attended only by the speaker’s office staff, doctors and staff from pain management
19 clinics, or Insys employees. Attendees often included colleagues and family
20 members of the speakers and Insys employees. Many of the events were held in
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1 restaurants where large sums of money were spent on expensive meals and alcoholic
2 beverages.

3
4 39. The eligibility requirements to participate in the ISP depended almost
5 exclusively on the amount of Subsys prescriptions the providers wrote. To illustrate,
6 in July 2012, Alex Burlakoff, Insys's North Carolina based Vice President of Sales,
7 sent a text message to Relator Guzman stating, "Don't worry about Dr Banchik or
8 Dr Vendrys's speaking abilities. They do not need to be good speakers, they need
9 to write a lot of Subsys."¹³
10

11
12 40. ISP providers consistently showed a spike in Subsys prescriptions
13 following initial enrollment therein.

14
15 41. The following paragraphs are examples of speaker programs and the
16 kickbacks that Insys has provided to induce providers to prescribe Subsys. These
17 examples of kickbacks paid by Insys are not intended to be comprehensive or
18 complete and do not fully describe or identify each and every action of Insys that
19 caused the submission of false or fraudulent claims to the Intervening States'
20 Medicaid programs or involved the use of false and fraudulent records or statements
21 related thereto. The Intervening States specifically incorporate by reference the
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27 ¹³ *United States ex rel. Guzman v. Insys Therapeutics, Inc.*, 13-cv-5861 (C.D. Cal.), Compl. ¶ 70.
28

1 allegations regarding speaker programs contained in Paragraphs 43 through 139 of
2 the Complaint in Intervention of the United States.¹⁴

3
4 42. The California Medicaid program reimbursed providers over \$8 million
5 for Subsys claims.

6 43. A former California sales representative for Insys who personally
7 attended and witnessed speaker programs said the audience was comprised of friends
8 and relatives of the doctor speaking. The sales representatives would regularly add
9 fictional names to the list of the program's attendees. He explained, "To me, the
10 speaker program was just a party."
11

12
13 44. CMS records show that between 2014 and 2017, Dr. R.K.,¹⁵ an
14 osteopathic physician specializing in physical medicine and rehabilitation, reported
15 receiving \$137,049.50 in speaking fees from Insys, all related to Subsys. During the
16 same period, Dr. R.K. was the tenth highest Medi-Cal¹⁶ prescriber of Subsys; Medi-
17 Cal reimbursed providers a total of \$235,859.26 for Subsys claims resulting from
18 Dr. R.K.'s prescriptions.
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23 ¹⁴ Where indicated by footnote or other document reference throughout the Complaint, certain
24 allegations in this Complaint are based on facts alleged in other cases or matters involving Insys
25 or Insys employees. The Intervening States represent that to the best of their knowledge,
26 information, and belief, those factual contentions have evidentiary support or will likely have
27 evidentiary support after a reasonable opportunity for further investigation or discovery.

28 ¹⁵ In some instances throughout this Complaint, providers and Insys employees are referenced by
first and last initial. The Intervening States will provide Defendant Insys with a list identifying
the names of the individuals referenced by initials herein.

¹⁶ Medi-Cal is California's State Medicaid Program.

1 45. The Colorado Medicaid Program reimbursed providers over \$2.6
2 million for Subsys claims.

3 46. In Colorado, Insys paid several physicians hundreds of thousands of
4 dollars ostensibly for their participation as presenters in speaker programs. One such
5 Colorado physician issued a large percentage of all of the Subsys prescriptions
6 reimbursed by Colorado Medicaid. Few of the physician's patients suffered from
7 cancer, let alone breakthrough cancer pain. In concert with Insys, the physician was
8 a strong advocate (and prescriber) of Subsys for a wide range of pain conditions, in
9 direct contradiction to the product's FDA-approved label. When new managers of
10 his practice decided to prohibit off-label prescribing of Subsys, the physician
11 responded adamantly against the decision in a long letter, and copied Insys in on his
12 efforts.

13 47. Communications between the physician and the company show that he
14 was eager to assist Insys and its sales representatives to increase business and
15 prescriptions of Subsys. In return, the company sent the physician on numerous
16 speaker programs in Colorado and elsewhere. Insys representatives were in close
17 contact with the physician, sometimes daily or several times per day, to set up these
18 programs. At times, these communications, often via text message, were intermixed
19 with demands by the physician to follow up on his honoraria payments, or to help
20 obtain approvals for patient prescriptions for Subsys. In one text message, an Insys
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1 representative thanked the physician for his presentation at a Colorado provider's
2 office, explaining that the provider was one of the "targets" of the company's local
3 sales representative. More than once, the physician coordinated with Insys
4 salespeople not only to set up more speaker opportunities, but to intervene on behalf
5 of his patients and to help Insys sales people meet their goals.
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8 48. At Insys's urging, the physician spoke frequently, and at many types of
9 physician offices. He spoke primarily to Colorado medical practices that did not
10 specialize in cancer, and sometimes his presentations were given to very few people
11 who were prescribers. He issued many prescriptions for Subsys to Colorado patients
12 without cancer, including orthopedic and accident patients, chronic headache
13 patients, and a patient with a varicose vein condition. One record shows that he
14 attempted to introduce a Colorado patient in 2016 to Subsys at a 600 mcg dose,
15 which is at flagrant odds with the titration instructions provided on the product's
16 label, which stated that all Subsys patients must start at 100 mcg (with exceptions
17 not relevant here). Another record shows him starting a different patient at a 400
18 mcg dose of Subsys.
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22 49. The physician issued many Subsys prescriptions to Colorado Medicaid
23 clients, whose prescriptions were submitted to Colorado Medicaid by pharmacies
24 located in Colorado.
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1 50. The Indiana Health Coverage Programs (“IHCP”) reimbursed
2 providers over \$2.7 million for Subsys claims.

3 51. During the years 2013 to 2016, Insys paid five Indiana physicians more
4 than \$324,000 in speaker fees. These five doctors accounted for nearly 60% of the
5 Subsys prescriptions paid for by the IHCP.
6

7 52. The Minnesota Medical Assistance (Medicaid) program reimbursed
8 providers over \$565,000 for Subsys claims.
9

10 53. From July 2013 to September 2015, Insys paid two Minnesota
11 physicians over \$43,000 in speaker fees for 36 ISP events. From July 2013 to
12 February 2017, these physicians, or their physician assistants or nurse practitioners,
13 were visited hundreds of times by Insys sales representatives and wrote over 90% of
14 the 665 Subsys prescriptions issued by Minnesota providers. Neither of these
15 physicians were oncologists and the vast majority of their patients were not cancer
16 patients.¹⁷
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19 54. Of the 36 Speaker Program events led by Minnesota prescribers, not
20 one was attended by an oncologist. For some events, Insys was unable to produce
21 evidence that any prescribers attended at all.¹⁸
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27 ¹⁷ *State of Minnesota v. Insys Therapeutics, Inc.*, 27-CV-18-9081, Compl. ¶¶ 127, 129, 134-37.

28 ¹⁸ *Id.* at ¶¶ 143-144.

1 55. One Minnesota provider was visited by Insys’s sales representatives 16
2 times in a ten-month period. In March 2017, this provider signed a Stipulation and
3 Order with the Minnesota Board of Medical Practice agreeing that she prescribed
4 medication and increased doses of narcotics without documenting a medical
5 rationale and prescribed Subsys at doses that exceeded the recommended initial dose
6 without medical justification. The provider also admitted that she prescribed Subsys
7 to multiple patients without enrolling in the required TIRF-REMS Access
8 program.¹⁹

9 56. The New York Medical Assistance Program (“NY Medicaid”) program
10 reimbursed providers over \$3.4 million for Subsys claims.

11 57. For the years 2013-2017, Insys reported making 6,488 payments to
12 New York doctors totaling \$1,898,914.11. Insys paid five New York doctors almost
13 half of that—\$865,144.12. Each of those five doctors has since been charged by the
14 United States for accepting bribes from Insys to prescribe Subsys, as set forth in an
15 indictment that was unsealed in the United States District Court for the Southern
16 District of New York on March 16, 2018.²⁰

17 58. One of the five charged on March 16, 2018 is Dr. Jeffrey Goldstein,
18 who wrote 22 prescriptions for Subsys between October 2013 and January 2016.

19 ¹⁹ *Id.* at ¶ 49.

20 ²⁰ *USA v. Freedman, et al.*, 18-cr-0217 (S.D.N.Y.).

1 NY Medicaid paid \$429,081.80 for the prescriptions. Several of those claims were
2 for high quantities (up to 240 per prescription) of Subsys at high dosages, including
3 11 separate prescriptions for 1,600 mcg sprays—the highest dosage available. Insys
4 reported payments to Goldstein of no less than \$216,086.85, all made as part of the
5 unlawful kickback scheme to induce Goldstein to improperly prescribe Subsys.
6

7
8 59. Another high prescriber of Insys in New York, Dr. Ernesto Lopez, was
9 arrested pursuant to felony a complaint on November 2, 2017. An indictment was
10 filed against him on January 3, 2018.²¹ Lopez was charged with diverting oxycodone
11 and various fentanyl products through his medical practice. Insys representatives
12 visited that practice many times, reporting 152 separate payments to Lopez as part
13 of the unlawful kickback scheme to induce Lopez to improperly prescribe Subsys.
14 Lopez wrote 67 Subsys prescriptions between March 2015 and March 2017 for
15 which NY Medicaid paid \$884,889.34.
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18 60. The North Carolina Medicaid Program reimbursed providers over \$4.8
19 million for Subsys claims.
20

21 61. Insys paid kickbacks to North Carolina doctors and medical providers
22 in the form of speaker fees, meals, and travel reimbursements to induce them to
23 prescribe Subsys to North Carolina Medicaid recipients. The speakers and attendees
24 at the program often did not treat cancer patients.
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²¹ *USA v. Lopez et al.*, 18-cr-0006 (S.D.N.Y.).

1 62. On January 14, 2013, Insys sponsored a speaker program at the
2 Carolina Headache Institute, a headache subspecialist group in Chapel Hill, North
3 Carolina. A physician specializing in neurology, Dr. D.C., promoted Subsys to these
4 headache specialists. No oncology specialists attended the speaker program.
5

6 63. On July 25, 2013, Insys sponsored a speaker program in Winston-
7 Salem. The physicians that attended the program specialized in neurological
8 diseases, not oncology.
9

10 64. Physician assistant J.W., who practiced in Winston-Salem, North
11 Carolina, spoke at numerous speaker programs. In exchange for participating in the
12 speaker programs, J.W. was paid honorarium fees and received free meals. After
13 Insys started paying J.W. speaker fees, J.W. prescribed Subsys off-label to several
14 North Carolina Medicaid recipients.
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17 65. The Virginia Medicaid program reimbursed providers over \$1.1 million
18 for Subsys claims.
19

20 66. From 2012 through 2017, Insys made 3,390 payments to, or for the
21 benefit of, Virginia physicians and other providers totaling more than \$372,000. Of
22 those payments, 133 were for speaker fees, speaker training fees, or consulting fees,
23 totaling more than \$265,000.
24

25 67. Dr. N.H. is a pain management doctor licensed to practice medicine in
26 the State of New York, the Commonwealth of Virginia, and Washington, District of
27
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1 Columbia. Dr. N.H. maintained an office and practice in the Commonwealth of
2 Virginia at all times relevant to this Complaint.

3 68. From 2012 through 2017, Insys paid Dr. N.H. more than \$80,000 in
4 speaking fees and more than \$10,000 in consulting fees, and also paid (or otherwise
5 provided) travel expenses and food and beverage costs of more than \$15,000 for Dr.
6 N.H.
7

8 69. Many, if not all, of the dozens of speaker programs for which Insys paid
9 Dr. N.H., including but not limited to those that took place in the Commonwealth of
10 Virginia, were in fact shams and were actually kickbacks to induce Dr. N.H. and
11 other providers to prescribe Subsys. As described below, many of the events took
12 place in expensive restaurants and many of the attendees were repeat attenders of
13 Dr. N.H.'s programs.
14

15 70. For example, on or about January 31, 2013, a speaker program featuring
16 Dr. N.H. was held at The Capital Grille in McLean, Virginia. The receipt from The
17 Capital Grille indicates that more than \$1,450 was spent for 14 guests, including
18 more than \$200 on wine. Among the attendees of this event were Dr. H.B., Dr. L.T.,
19 several employees of a pain management clinic, and Insys employee S.B. Dr. H.B.
20 is a pain management doctor and attendee of multiple speaker events in Virginia
21 involving Dr. N.H. The representative evaluation form from S.B. states that "I am
22 expecting the continued support of Dr [N.H.], and I am anxious to set up more dinner
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1 meetings with him.” Insys paid Dr. N.H. a speaker fee of \$1,000 for this program
2 on or about January 31, 2013.

3
4 71. Dr. L.T. is a pain management doctor who is believed to be the spouse
5 of Insys employee S.T., formerly known as S.B. as identified in ¶ 70 above.
6 Including the January 31, 2013 event, Dr. L.T. is listed on the sign-in sheets for at
7 least seven Insys speaker programs from 2013 through 2016, all of which took place
8 at restaurants.

9
10 72. On or about April 25, 2013, a speaker program featuring Dr. N.H. was
11 held at The Capital Grille in McLean, Virginia. The receipt from The Capital Grille
12 indicates that more than \$1,060 was spent for 12 guests. Among the attendees of the
13 program were Dr. H.B., Dr. L.T., A.H. (who shares the last name of Dr. N.H. and
14 whose occupation is listed as “med. avertizing [sic]”), and Insys employees S.T. and
15 Sunrise Lee. The representative evaluation form from S.T. states that “I anticipate
16 that Dr [N.H.] will continue to be a huge Subsys advocate.” Insys paid Dr. N.H. a
17 speaker fee of \$1,600 for this program on or about April 25, 2013.

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21 73. On or about May 7, 2013, a speaker program featuring Dr. N.H. was
22 held at a medical office in Arlington, Virginia. Among the attendees of the event
23 were Dr. A.C., Insys employee S.T., and a number of office staff members, including
24 “receptionist,” “office biller,” and “medical assistant.” Dr. A.C. is a pain
25 management doctor and attendee of multiple speaker events in Virginia involving
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1 Dr. N.H. The representative evaluation form from S.T. states that “[al]though I am
2 not 100% sure that the physicians at the Surgical center will use Subsys, I do know
3 that all chronic pain patients will be referred to Dr. [N.H.] and he will be able to take
4 care of their pain that way.” Insys paid Dr. N.H. a speaker fee of \$1,600 for this
5 program on or about May 7, 2013.
6

7
8 74. On or about August 22, 2013, a speaker program featuring Dr. N.H.
9 was held at a pain management clinic in McLean, Virginia. Among the attendees of
10 the event were Dr. A.C., Dr. H.B., Insys employee S.T., and a number of office staff,
11 including “front desk,” “med student,” “case mgr,” two medical assistants, and a
12 nurse. The representative evaluation form from S.T. states that “I know that Dr
13 [N.H.] will continue to be a big supporter of Subsys and that the entire office finally
14 feels comfortable with how the entire ‘system’ is working, from the initial Rx to the
15 reimbursement center to the PA [prior authorization] process.” Insys paid Dr. N.H.
16 a speaker fee of \$1,600 for this program on or about August 30, 2013.
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20 75. On or about November 21, 2013, a speaker program featuring Dr. N.H.
21 was held at the pain management clinic of Dr. J.F. in Falls Church, Virginia. Among
22 the attendees of the program were Dr. J.F. and a number of office staff, including
23 “office,” “pt. coordinator,” “reception,” “case mgr,” “lab tech,” and several medical
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1 assistants. Insys paid Dr. N.H. a speaker fee of \$1,600 for this program on or about
2 November 25, 2013.²²

3
4 76. On or about December 12, 2013, a speaker program featuring Dr. N.H.
5 was held at Dr. N.H.'s pain management clinic in Falls Church, Virginia. Among
6 the attendees of the program were Dr. A.C., Dr. H.B., Insys employee S.T., and a
7 number of Dr. N.H.'s office staff members, including "front desk," "admin," a nurse,
8 and several medical assistants. The representative evaluation form from S.T. states
9 that "I know that this office will continue to be a big supporter of Subsys and they
10 will continue to find patients within the practice whose medical history would make
11 them excellent Subsys candidates." Insys paid Dr. N.H. a speaker fee of \$1,600 for
12 this program on or about December 19, 2013.

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16 77. On or about August 21, 2014, a speaker program featuring Dr. N.H.
17 was scheduled to take place at the Braner Clinic in Falls Church, Virginia. An email
18 from Insys employee S.T. dated August 20, 2014 states that "the office told me that
19 the doctor in that office is going to be taking an 'impromptu' vacation.... Obviously
20 I will have to reschedule this program." Insys paid Dr. N.H. a speaker fee of \$2,200
21 for this program on or about August 26, 2014, despite the fact that there are no
22 completed sign-in sheets and it appears as though the event never took place.
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27 ²² Dr. J.F.'s license is suspended indefinitely pursuant to a Consent Order entered into with the
28 Virginia Board of Medicine due to Dr. J.F.'s opioid prescribing practices for several patients.

1 78. On or about April 23, 2015, a speaker program featuring Dr. N.H. was
2 held at the office of Dr. S.Y. in Alexandria, Virginia. Among the attendees of the
3 event were Dr. S.Y. and Dr. M.L., both internal medicine physicians, and a number
4 of office staff members, including “front desk,” “lab,” “pt. coordinator,” and
5 “recept.” The representative evaluation form from S.T. states that she was “[h]oping
6 for support from Dr. [Y], but @ least pt. referrals to [Dr. N.H].”
7
8

9 79. Also on or about April 23, 2015, a speaker program featuring Dr. N.H.
10 was held at a restaurant known as Gypsy Soul in Fairfax, Virginia. The receipt from
11 Gypsy Soul indicates that more than \$1,400 was spent for 13 guests, including \$390
12 designated on the receipt as “open drink.” Among the attendees of the event were
13 Dr. A.C., Dr. M.C. (a neurologist who shares the last name of Dr. A.C.), Dr. A.A.,
14 Dr. J.F., and Insys employee S.T. Insys paid Dr. N.H. two speaker fees (one for
15 \$1,100 and one for \$2,200) for the two April 23, 2015 speaker programs on or about
16 April 27, 2015.
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20 80. On or about November 12, 2015, a speaker program featuring Dr. N.H.
21 was scheduled to take place at Rays the Steaks in Arlington, Virginia. According to
22 receipts possessed by Insys, a “deposit” of \$250 was paid to Rays the Steaks on or
23 about November 3, 2015 (although a receipt suggests that four gift cards may have
24 been purchased) and a cancellation fee of \$350 was paid to Rays the Steaks on or
25 about November 12, 2015. Insys paid Dr. N.H. a speaker fee of \$2,200 for this event
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1 on or about November 16, 2015 and reimbursed Dr. N.H. \$26.45 for mileage on or
2 about December 9, 2015, despite the fact that there are no completed sign-in sheets
3 and it appears that the event never took place.
4

5 81. On or about November 13, 2015, a speaker program featuring Dr. N.H.
6 was held at Dr. A.A.'s pain management clinic in Alexandria, Virginia. The only
7 attendees of the event were Dr. N.H., Dr. A.A., a physical therapist, a medical
8 assistant, and Insys employee S.T. Insys paid Dr. N.H. a speaker fee of \$2,200 for
9 this program on or about November 16, 2015.
10

11 82. Since 2012, the Virginia Medicaid program has paid over \$10,000 for
12 Subsys that was prescribed by Dr. N.H. More specifically, between approximately
13 March 2014 and August 2015, Dr. N.H. wrote Subsys prescriptions for Patient
14 #VA1, a Virginia Medicaid beneficiary.²³ Virginia Medicaid paid six claims for
15 Patient #VA1's Subsys prescribed by Dr. N.H. for more than \$10,000.
16
17

18 83. In addition, Dr. H.B., a pain management doctor and attendee of
19 multiple speaker events in Virginia involving Dr. N.H., subsequently wrote Subsys
20 prescriptions that were paid for by Virginia Medicaid. More specifically, Dr. H.B.
21 wrote one Subsys prescription in or about December 2013 for Patient #VA2, a
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23
24

25 ²³ Patient identities are not provided here to protect patient privacy and confidential health
26 information. Upon entry of an appropriate protective order, the Commonwealth of Virginia will
27 provide Defendant Insys with a list identifying the names of the patients identified herein and
28 details regarding the claims submitted to Virginia Medicaid for those patients.

1 Virginia Medicaid beneficiary, and one Subsys prescription in or about May 2014
2 for Patient #VA1, a Virginia Medicaid beneficiary. Virginia Medicaid paid two
3 claims associated with these Subsys prescriptions for more than \$2,400.
4

5 84. Dr. H.B. was also compensated (or otherwise provided) more than
6 \$57,000 by Insys from 2013 through 2016, including more than \$51,000 in speaker
7 fees and more than \$4,000 for food and beverage.
8

9 85. Furthermore, Dr. A.C., a pain management doctor and attendee of
10 multiple speaker events in Virginia involving Dr. N.H., subsequently wrote Subsys
11 prescriptions that were paid for by Virginia Medicaid. More specifically, Dr. A.C.
12 wrote Subsys prescriptions for Patient #VA1, a Virginia Medicaid beneficiary,
13 between approximately December 2014 and January 2016, and for Patient #VA2, a
14 Virginia Medicaid beneficiary, between approximately December 2013 and January
15 2014. Virginia Medicaid paid 12 claims associated with these Subsys prescriptions
16 (10 paid claims for Patient #VA1 and two paid claims for Patient #VA2) for more
17 than \$38,000.
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21 86. Dr. A.C. is or was an employee of, or was otherwise associated with,
22 Dr. N.H.'s pain management practice.
23

24 87. Dr. A.C. was compensated (or otherwise provided) more than \$700 for
25 food and beverage by Insys from 2013 through 2016.
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1 88. Dr. C.B. operates a pain management clinic in Richmond, Virginia. Dr.
2 C.B. is licensed to practice medicine in the Commonwealth of Virginia, and
3 maintained an office and practice in the Commonwealth of Virginia at all times
4 relevant to this Complaint.
5

6 89. From 2013 through 2015, Insys paid Dr. C.B. more than \$20,000 in
7 speaking fees and \$2,500 in consulting fees, and also paid (or otherwise provided)
8 travel expenses and food and beverage costs of more than \$4,000 for Dr. C.B.
9

10 90. Many, if not all, of the more than a dozen Virginia speaker programs
11 for which Insys paid Dr. C.B. were in fact shams and were actually kickbacks to
12 induce Dr. C.B. and other providers to prescribe Subsys. As described below, many
13 of the events took place in expensive restaurants and many of the attendees were
14 repeat attenders of Dr. C.B.'s programs.
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17 91. For example, on or about June 27, 2013, a speaker program featuring
18 Dr. C.B. was held at Fleming's Prime Steakhouse in Richmond, Virginia. The
19 receipt from Fleming's for this event indicates that approximately \$350 was spent
20 on food and drinks for four guests. The only attendees of the program were Dr. C.B.,
21 Physician Assistant A.S. from Dr. C.B.'s office, and Insys employees C.J. and B.R.
22 Insys paid Dr. C.B. a speaker fee of \$1,000 for this program on or about June 27,
23 2013.
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1 92. On or about July 16, 2013, a speaker program featuring Dr. C.B. was
2 held at The Boathouse at Rocketts Landing in Richmond, Virginia. The receipt from
3 The Boathouse for this event indicates that approximately \$500 was spent on food
4 and drinks, including numerous alcoholic beverages, for six guests. The attendees
5 of the program were Dr. C.B., Physician Assistant A.S. from Dr. C.B.'s office, a
6 registered nurse from Dr. C.B.'s office, a nurse practitioner who appears to be
7 associated with a pain management practice run by Dr. B.S., and Insys employees
8 C.J. and B.R. Insys paid Dr. C.B. a speaker fee of \$1,000 for this program on or
9 about July 16, 2013.

10 93. On or about August 22, 2013, a speaker program featuring Dr. C.B. was
11 held at Fleming's Prime Steakhouse in Richmond, Virginia. The receipt from
12 Fleming's for this event indicates that nearly \$500 was spent on food and drinks for
13 five guests. The attendees of the program included Dr. C.B., a pain management
14 doctor (Dr. J.B.), and two medical assistants who appear to be associated with Dr.
15 J.B.'s practice. Insys paid Dr. C.B. a speaker fee of \$1,000 for this program on or
16 about August 30, 2013. A later email indicated that Insys was "targeting" Dr. J.B.,
17 a pain management doctor, as "a very prominent doctor in the Richmond area."

18 94. On or about August 27, 2013, a speaker program featuring Dr. C.B. was
19 held at The Boathouse at Rocketts Landing in Richmond, Virginia. The receipt from
20 The Boathouse for this event indicates that more than \$650 was spent on food and
21

1 drinks, including numerous alcoholic beverages, for seven guests. The attendees of
2 this speaker program were Dr. C.B., Insys employee C.J., and five people who
3 appear to be associated with Dr. B.S.'s pain management clinic, including Dr. B.S.
4 and several of his staff. Insys paid Dr. C.B. a speaker fee of \$1,000 for this program
5 on or about August 30, 2013.
6

7
8 95. Two attendees of the August 27, 2013 event, who appear to be staff
9 members of Dr. B.S., also each attended at least two subsequent speaker events
10 featuring Dr. B.S. as the speaker.
11

12 96. Dr. B.S. was also paid at least \$8,000 in speaker fees by Insys from
13 2013 through 2014.
14

15 97. On or about September 10, 2013, a speaker program featuring Dr. C.B.
16 was held at Fleming's Prime Steakhouse in Richmond, Virginia. The receipt from
17 Fleming's for this event indicates that more than \$700 was spent on food and drinks
18 for seven guests. The attendees of this speaker program included Dr. C.B., Physician
19 Assistant A.S. from Dr. C.B.'s office, two medical assistants who appear to be
20 associated with Dr. C.B.'s office, a psychiatrist, and Insys employee C.J. Insys paid
21 Dr. C.B. a speaker fee of \$1,000 for this program on or about August 30, 2013.
22
23

24 98. On or about September 19, 2013, a speaker program featuring Dr. C.B.
25 was held at The Boathouse at Rocketts Landing in Richmond, Virginia. The receipt
26 from The Boathouse indicates that nearly \$530 was spent at this event. The attendees
27
28

1 of this speaker program were Dr. C.B., Physician Assistant A.S. from Dr. C.B.'s
2 office, three technicians with the same address as Dr. C.B., and Insys employee C.J.
3 Insys paid Dr. C.B. a speaker fee of \$1,000 for this program on or about September
4 25, 2013.
5

6 99. On or about October 8, 2013, a speaker program featuring Dr. C.B. was
7 held at The Boathouse at Rocketts Landing in Richmond, Virginia. The attendees
8 of the program were Dr. C.B., Physician Assistant A.S. from Dr. C.B.'s office, a
9 medical assistant and a nurse who both appear to be associated with Dr. B.S.'s pain
10 management clinic, and Insys employee C.J. Insys paid Dr. C.B. a speaker fee of
11 \$1,000 for this program on or about October 17, 2013.
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14 100. On or about January 27, 2014, a speaker program featuring Dr. C.B.
15 was held at Old Original Bookbinder's in Richmond, Virginia. The receipt from
16 Bookbinder's indicates that \$600 was spent for two guests on oysters, lobster,
17 desserts, and numerous alcoholic drinks, among other items. According to Insys's
18 records, no sign-in sheets were turned in by Insys employee C.J. for this event prior
19 to the termination of his employment with Insys. Insys paid Dr. C.B. a speaker fee
20 of \$1,000 for this program on or about February 6, 2014.
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24 101. On or about June 18, 2015, a speaker program featuring Dr. C.B. was
25 held at Hondo's Prime Steaks in Glen Allen, Virginia. The receipt from Hondo's
26 indicates that more than \$1,200 was spent on food and drinks for 14 guests. The
27
28

1 attendees of the program were Dr. C.B., a physician, a number of medical assistants
2 and nurses, and Insys employees J.W. and P.G. Insys paid Dr. C.B. a speaker fee of
3 \$1,900 for this program on or about June 22, 2015.
4

5 102. On or about June 25, 2015, a speaker program featuring Dr. C.B. was
6 held at Hondo's Prime Steaks in Glen Allen, Virginia. The receipt from Hondo's
7 indicates that approximately \$1,065 was spent on food and drinks for 10 guests. The
8 attendees of this speaker program included Dr. C.B., a number of nurses and other
9 office personnel, and Insys employee J.W. Insys paid Dr. C.B. a speaker fee of
10 \$1,900 for this program on or about June 29, 2015.
11
12

13 103. Since 2012, the Virginia Medicaid program has paid over \$140,000 for
14 Subsys that was prescribed by Dr. C.B. More specifically, between approximately
15 November 2015 and February 2017, Dr. C.B. wrote Subsys prescriptions for Patient
16 #VA3, a Virginia Medicaid beneficiary, and Virginia Medicaid paid 28 claims
17 associated with these Subsys prescriptions for more than \$140,000.
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20 104. In addition, the physician who attended the June 18, 2015 speaker event
21 featuring Dr. C.B. subsequently wrote Subsys prescriptions that were paid for by
22 Virginia Medicaid. More specifically, between approximately September 2015 and
23 December 2016, this physician wrote Subsys prescriptions for Patient #VA4, a
24 Virginia Medicaid beneficiary, and Virginia Medicaid paid 18 claims associated
25 with these prescriptions for more than \$174,000.
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1 105. This physician was paid (or otherwise provided) more than \$680 for
2 food and beverage by Insys in 2015, including the June 18, 2015 event at Hondo's
3 describe above, and more than \$295 for food and beverage by Insys in 2016.
4

5 106. On various other dates from at least 2013 forward, Insys paid speaker
6 fees, consulting fees, and otherwise reimbursed or compensated other doctors or
7 medical professionals for speaker events in the Commonwealth of Virginia,
8 including out-of-state speakers brought in to participate in speaker program events
9 in Virginia.
10

11 107. For example, on numerous occasions in 2013 and 2014, Insys paid
12 speaker fees, consulting fees, and otherwise reimbursed or compensated Dr. S.O., a
13 pain management doctor, for speaker program events in Virginia. Insys paid Dr.
14 S.O. approximately \$17,000 in speaker and consulting fees in 2013 and more than
15 \$18,000 in speaker fees in 2014. Furthermore, despite public news reports indicating
16 that Dr. S.O. was arrested for improper narcotic prescribing practices on or about
17 July 2014, Insys subsequently paid Dr. S.O. a speaker program fee of \$3,750 on or
18 about October 31, 2014 and subsequently reimbursed or otherwise provided food
19 and beverage payments for Dr. S.O. on numerous occasions from 2014 through
20 2017.
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25 108. On at least three separate occasions in 2016, Insys paid for or otherwise
26 reimbursed Dr. W.A., a doctor from Alabama, for travel to Virginia to serve as a
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1 speaker for Insys's speaker program. Dr. W.A. served as a speaker for two events
2 each on or about August 24, 2016; September 20, 2016; and November 15, 2016, at
3 different locations in Virginia. In emails from August of 2016, Dr. W.A.'s travel to
4 Virginia was approved by Insys because "[t]here is [sic] no MD speakers in
5 Virginia" and Dr. W.A.'s "flight is within Gulf Coast region." Insys paid Dr. W.A.
6 more than \$20,000 in speaker fees for these six events, and Insys also paid or
7 otherwise reimbursed thousands of dollars for airfare and travel costs for Dr. W.A.
8 In total, Insys paid Dr. W.A. more than \$148,000 in speaker and consulting fees from
9 2014 through 2016.

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13 109. On multiple occasions from 2014 through 2016, Insys paid or otherwise
14 reimbursed Dr. M.A., a pain management doctor from Maryland, for travel to
15 Virginia to serve as a speaker for Insys's speaker program. For example, Dr. M.A.
16 served as a speaker for programs that took place on or about January 15, 2014;
17 January 16, 2014; June 5, 2014; February 10, 2015; June 22, 2015; April 7, 2016;
18 and June 22, 2016, at different locations in Virginia. Dr. M.A. was paid more than
19 \$12,000 in speaker fees for these seven events. In total, Insys paid Dr. M.A. more
20 than \$60,000 in speaker and consulting fees from 2013 through 2016.
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1 D. Insys Focused on the Importance of Speaker Programs’ “Return on
2 Investment”

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4 110. The purpose of Insys’s Speaker Program was not to identify appropriate
5 speakers and target audiences, nor was it geared toward promoting safe, on-label use
6 of Subsys. Instead, Insys was focused on the expected “return on investment,” or
7 “ROI,” from the speaker programs, meaning whether the speaker programs would
8 translate to increased Subsys sales.
9

10 111. Speaking opportunities were offered to providers based on the volume
11 of Subsys prescriptions they wrote. Therefore, Insys constantly monitored
12 practitioners enrolled in the ISP to make sure the number of speaking opportunities
13 offered to each practitioner was appropriate in light of the amount of Subsys
14 prescriptions they produced. Insys would, for example, reduce the number of
15 scheduled speaking events for practitioners if Insys was unhappy with the
16 practitioners’ volume of Subsys prescriptions, and would increase scheduled
17 speaking events for practitioners who pushed larger quantities of prescriptions.²⁴
18
19
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21 112. The following paragraphs describe illustrative examples of Insys’s
22 focus on “ROI” and its efforts to boost sales of Subsys, including emails from Insys
23 management emphasizing the importance of the expected “ROI” from speaker
24 programs. These examples are not intended to be a comprehensive or complete list.
25
26

27 ²⁴ *USA v. Kapoor et al.*, 16-cr-10343 (D. Mass.), Indict. ¶¶ 14-17, 65-67.
28

1 113. On or about September 17, 2012, Burlakoff sent an email to all sales
2 representatives entitled "Insys Speaker Programs." The email copied Michael
3 Babich, President and CEO of Insys, and M.N., Insys's Vice President of Marketing,
4 and John Kapoor, founder and then board member of Insys. In the email, Burlakoff
5 highlighted the importance of return on investment from the speaker programs,
6 including Burlakoff's comment that "[i]f you cannot guarantee that this program will
7 yield positive results, the program should not take place." Burlakoff further stated:
8

9 It is my understanding that many of you have been strongly urged to
10 schedule these programs, as if the effort of simply conducting a speaker
11 program would serve as a 'feather in your cap'. *Activity* does not
12 necessarily equate to *productivity*. These programs have been offered
13 to you as the #1 opportunity to grow your business, unfortunately - a
14 scheduled speaker program does **not** by any means solidify a return on
15 investment. Please understand that Insys sales representatives do not
16 get paid to be 'active', Insys sales representatives get paid to produce
17 tangible results. The hungry/motivated sales representatives will be
18 facilitating as many ISP's as humanly possible, because they know this
19 is the ONLY likely road to the Presidents Club. The sales
20 representatives that are not willing to take a calculated risk, will
21 inevitably find themselves in the middle or bottom of the pack (year
22 after year).

23 Burlakoff continued:

24 If your speaker is not an expert with the utilization of Subsys in his or
25 her clinical practice, then your speaker need not speak for Insys
26 anymore! I would venture to say that if your speaker does not have at
27 least 20 patients on Subsys (QTD), he or she should not be booked to
28 speak at this juncture. You should cancel or suspend your
programs until you and your manager have had ample chance to think
this investment entirely through.

1 Burlakoff noted that “speaker programs are the only way to truly solidify yourself
2 as a top performing sales representative,” “[s]peaker programs are a ‘gift’, but they
3 are not to be taken for granted,” and “[o]ur goal is to ensure all speaker programs
4 are a success for each and every Insys sales representative.” Burlakoff concluded
5 the email by stating, “[r]est assured, we will provide you the specific ‘road map’ you
6 will need to follow in order to make this level of success a consistent reality!”
7
8

9 114. The same day, Burlakoff emailed a sales representative in response to
10 a question about a speaker program. Burlakoff instructed the representative about
11 scheduling future speaker programs and stated that “[y]our local speaker should be
12 your ‘business partner’. You do not work for him, nor does he work for you. You
13 are partners in this endeavor, if your speaker does not see it this way..... (then it
14 is time to identify another speaker).”
15
16

17 115. On or about September 26, 2012, Burlakoff sent an email to Joseph
18 Rowan, East Regional Director, about speaker programs, copying Regional Sales
19 managers Babich and M.N., among others. The email addressed deficiencies in sales
20 representatives’ speaker program requests, such as a lack of specificity with regard
21 to expected attendees and catering. Burlakoff noted, “[t]he more work the
22 representative puts into planning the program up front, the better the return on
23 investment in the end. I am sure we would all agree that ROI is our #1 priority when
24 the program is all said and done!”
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1 116. Furthermore, on or about October 18, 2012, an Insys executive
2 forwarded an email from an Insys sales representative to all Insys sales managers
3 that recommended certain higher volume prescribers to be speakers while canceling
4 speaking events for lower volume prescribers. He remarked, “[g]reat example of
5 how we need to pro-actively manage our speaker data base by both adding and soft
6 deleting speakers on an ongoing basis....”²⁵
7
8

9 117. On or about December 1, 2012, Sunrise Lee, the Sales Manager for the
10 Mid-Atlantic region at the time, emailed the Mid-Atlantic sales team, copying
11 Burlakoff, about scheduling speaker programs for 2013. Lee stated that “[i]t’s time
12 to get those ISP’s for 2013 on the books. I hope that you all know by now, the faster
13 you have ISP’s scheduled on the books the better. I want as many 2013 ISP’s as
14 possible to take place from January through March. ... I will only approve the ISP’s
15 that I feel are adequate for return on investment....”
16
17

18 118. On December 10, 2012, Insys’s Vice President of Marketing sent an
19 email to two Insys executives with an attachment entitled, “Speaker Bureau
20 Assessment.” The attachment computed the ratio of return on investment (“ROI”) for each speaker enrolled in the Speaker Program. The ROI ratio was calculated
21 using the amount of speaker fees, or, “honoraria”, paid to each individual speaker
22 for their participation in the Speaker Program compared to the net revenue generated
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27 ²⁵ *USA v. Kapoor et al.*, 16-cr-10343 (D. Mass.), Indict. ¶ 194.
28

1 by prescriptions each speaker had written. The attachment noted, “Speakers with
2 programs generated ~6xs more revenue per prescriber than those with no programs.”
3 Two days later on December 12, 2012, Insys’s Vice President of Marketing sent an
4 email to Insys’s Chief Financial Officer (“CFO”) and another Insys executive with
5 a PowerPoint attached entitled, “2013 Proposed Marketing Budget.” The
6 PowerPoint noted a “7.5:1 ROI, Honoraria to Net Rev.” It warned that speakers with
7 less than a 2:1 ROI ratio had been “flagged,” and it identified candidates to “soft
8 delete” from the Speaker Program.²⁶
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12 119. On or about March 7, 2013, Burlakoff sent an email to Regional Sales
13 Managers, copying Babich, along with a spreadsheet of January 2013 spending.
14 Burlakoff stated:
15

16 I am inclined to find myself more excited by the larger amounts of
17 money I see the managers spending, although – it all comes down to
18 ROI. If you are going to spend the most money, you should probably
19 by [sic] #1 in the region. Do not by [sic] shy, it takes money to make
20 money....

21 He suggested that they should “[s]pend some money and close some deals (that’s
22 what you were hired for)” and stated that “I want the managers to lead by setting
23 example / be aggressive! / take some financial risk!” Regarding sales
24 representatives, Burlakoff asked, “[i]s there a correlation (positive or negative) with
25 how much money the rep spent and their current ranking?” Burlakoff sent a follow-
26

27 ²⁶ *USA v. Kapoor et al.*, 16-cr-10343 (D. Mass.), Indict. ¶ 61.
28

1 up email the same day identifying the three highest-spending sales representatives,
2 noting that they “spent the most money as sales reps (thus far), both [sic] are in the
3 top 5 in the company. Again – we can’t help people that do not listen to the direction
4 we provide them.” One of those high-spending sales representatives was Karen Hill,
5 who pleaded guilty in or about July of 2017 to one count of conspiracy to violate the
6 AKS in connection with her work at Insys.²⁷
7

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9 120. On or about March 11, 2013, an Insys sales representative emailed
10 Rowan to ask about conducting a lunch program at an oncology practice. The sales
11 representative stated:
12

13 While the lunch will cost us approximately \$2000, getting an
14 oncologist’s support and experience with SUBSYS would open an
15 entire new opening for SUBSYS nationally. It only takes one
16 Oncologist, and I believe that with this lunch, we will find no less than
17 ONE Oncologist who immediately thinks if [sic] patients that can
18 benefit from SUBSYS.

19 Rowan sent the email to Burlakoff, who in turn sent it to M.N. M.N. responded, “I
20 fully support this initiative. I want to diligently track the return on investment here
21 [L]et’s summarize all ISPs flagged as Oncology and measure their return. I
22 would like to compare these to Pain programs as well.” As discussed in detail herein,
23 Subsys is and always has been approved by the FDA for breakthrough cancer pain
24 only, not general pain management.
25

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²⁷ *USA v. Karen Hill*, 17-cr-00139 (S.D. Ala.).
28

1 121. On or about March 14, 2013, Burlakoff sent an email to Regional Sales
2 Managers, copying Babich and M.N., regarding speaker program spending.
3 Burlakoff noted that “[h]alf of your reps do not produce any return on investment
4 from ‘ISP’s – as evidenced by the data presented from previous quarters. Why give
5 them program dollars - I do not understand? I am trying to make a statement here,
6 all in the world of business (is NOT fair).” Burlakoff continued, noting that “I am
7 tired of giving money to reps whom [sic] produce zero ‘return on investment’” and
8 “[t]hose whom [sic] do not produce ROI from programs should not be spending our
9 ISP dollars.....” Burlakoff concluded:
10
11

12 The fact that we are giving thousands of dollars to reps whom [sic] do
13 not understand the true value of an ISP is laughable. The notion that
14 we are in essence taking those same dollars away from reps whom [sic]
15 produce ROI from his or her ISP’s (time and time again is- extremely
16 depressing)[.] Let’s make the changes now and salvage this
17 opportunity for the sake of the company!

18 122. On or about March 28, 2013, an Insys employee emailed Babich and
19 Burlakoff regarding spending by sales representatives. In response, Burlakoff
20 forwarded the emails to Regional Sales Managers and noted that “I am happy to see
21 reps spend money, especially ‘new reps’ whom [sic] are clearly trying to jumpstart
22 their business. It is however more important that we are able to manage these reps
23 in a way that guarantees return on investment.”
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1 123. On or about October 30, 2013, Burlakoff emailed Regional Directors
2 and District Managers, copying Babich and M.N. among others, regarding the
3 allocation of Insys's speaker programs among districts. Burlakoff stated:
4

5 The moment your sales person is provided with the number of programs
6 he or she has for the quarter, everything should drop until he or she gets
7 every program secured down to the last detail. Their only focus should
8 be by [sic] securing their speaker programs. You as a management team
9 should be calling these reps hourly to make sure they are not dropping
10 the ball. The moment you sense they are not doing their job to
11 satisfaction, you re-allocate the program to someone on your team
12 whom will. This way, you as a manager do not lose the program to
13 another district or region.

14 Burlakoff noted that "[u]nfortunately, somewhere down the chain - people are still
15 not getting it. Everyone needs to understand this is a business, this is not 'little
16 league' where everyone gets a chance at bat and to play their favorite position."

17 Burlakoff further stated that "[t]he money was put on the table and some did not take
18 that opportunity seriously enough. When it comes to money 'in all facets of life', if
19 you don't take care of it - its dissapears [sic] in some way, shape, or form." Burlakoff
20 continued: "We are competing for time, focus, energy, and enthusiasm from every
21 one of our customers. When we do not feverishly confirm a program when given
22 the opportunity, our ability to maximize ROI diminishes daily." Burlakoff further
23 notes that "[w]e clearly failed to succeed in this initiative, and we will all suffer the
24 consequences in our bonus's [sic] accordingly."
25
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1 124. On or about October 27, 2014, Burlakoff sent an email to Regional
2 Directors and District Managers about spending by sales representatives. Burlakoff
3 noted, “I see some names of representatives that simply have never caught my
4 attention before as it pertains to being a leader in driving sales for Insys - YET they
5 appear to often times be leaders in spending the company's most valuable
6 resource dollars on a monthly basis.” Burlakoff continued:
7
8

9 I take no issue with those top sales performers whom also happen to be
10 at the top of the ‘spending’ list. This means the rep is using his or her
11 allocated Insys dollars to provide consistent Subsys related
12 educational ‘in services’ - in an effort to appropriately brief and support
13 our HCP’s in correlation with their expressed desire to utilize
14 Subsys....²⁸

15 E. Insys Focused on Increasing Sales Rather Than Patients with Cancer

16 125. Insys’s internal training and meeting materials highlight the company’s
17 efforts to increase Subsys sales and encourage higher dosing by providing an
18 incentive-laden compensation system that paid sales representatives potentially
19 large bonuses based on Subsys sales. The materials make no mention of targeting
20 cancer patients or ensuring appropriate dosing. Instead, they demonstrate that Insys
21 was focused on promoting higher doses of Subsys, higher numbers of Subsys
22 prescriptions, and increased market share for Subsys.
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27 ²⁸ *USA v. Kapoor et al.*, 16-cr-10343 (D. Mass.), Indict. ¶ 204; *USA v. Pearlman*, 17-cr-00027
28 (D. Conn.), Indict. ¶ 15.

1 126. As discussed supra at ¶ 37, Subsyst's FDA-approved labeling, designed
2 to protect patients, stated that prescribers should always start patients at a dose of
3 100 mcg. Insys tracked these initial doses and instructed its sales representatives to
4 titrate patients up when a prescriber wrote a so-called "low dose"—which Insys
5 considered to be 400 mcg or lower, or four times the approved initial dose—
6 regardless of whether the dose had been determined to be effective. Insys
7 improperly encouraged prescribers to quickly titrate patients up to even large
8 maintenance doses based on financial, rather than medical, rationale.²⁹

9 127. The following paragraphs illustrate Insys's efforts to facilitate Subsyst
10 prescriptions for off-label uses, including in high doses, and its incentive
11 compensation system to boost Subsyst sales. These examples are not intended to be
12 a comprehensive or complete list. Furthermore, the Intervening States specifically
13 incorporate by reference Paragraphs 140 through 146 of the Complaint in
14 Intervention of the United States.

15 128. In a PowerPoint presentation entitled "The SUBSYS Pay for
16 Performance Plan" for "Q2 2012," sales employees were instructed on how to
17 increase business and, as a result, increase their earnings. One slide entitled "How
18 Many Patients Can You Get" demonstrates how compensation increases based on
19

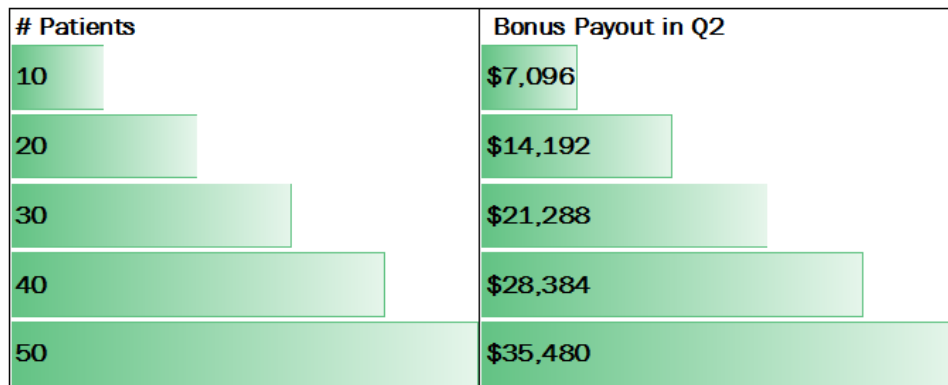
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27 ²⁹ *State of Minnesota v. Insys Therapeutics, Inc.*, 27-CV-18-9081, Compl. ¶¶ 80-88.

the number of patients acquired. Ten patients means a bonus payout of \$7,096, but 50 patients means a bonus payout of \$35,480:

How Many Patients Can You Get



More Patients = More \$\$\$!



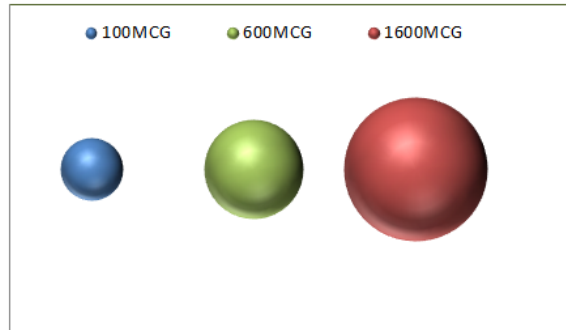
129. In another slide, sales employees were reminded that “Higher Doses = Higher Payouts!” and are asked to “[i]magine how your payout will differ if you sell a single script in either 100, 600 or 1600MCG”:

Don't Forget the Doses



Higher Doses = Higher Payouts !

Imagine how your payout will differ if you sell a single script in either 100, 600 or 1600MCG



130. In a later version of the PowerPoint presentation, entitled “SUBSYS Incentive Compensation Plan” for “Q3 2012,” sales employees were trained on how to increase Subsys business and boost earnings. One slide, entitled “How You Can Make Money in Q3,” included a bullet point, “Higher \$\$\$ / Script,” suggesting that “[m]ore units” and “[g]reater strength” were ways for sales staff to make more money. Another bullet point, “Higher Net \$ Sales,” encouraged the “[m]aximum number of scripts” and that sales employees should try to “keep the patient on” Subsys:

How You Can Make Money in Q3



Any of the following achievements will help you make money. Make all three happen and you will win BIG!

- **Higher \$\$\$ / Script**

- ✓ More units (90, 120, 180 ...)
- ✓ Greater strength (800MCG, 1200MCG, 1600MCG ...)

- **Higher Net \$ Sales**

- ✓ Maximum number of scripts
- ✓ Improve net-to-gross sales ratio (keep the patient on after initial free product, and successfully convert patient to insurance-paid)

- **Higher SUBSYS Market Share**

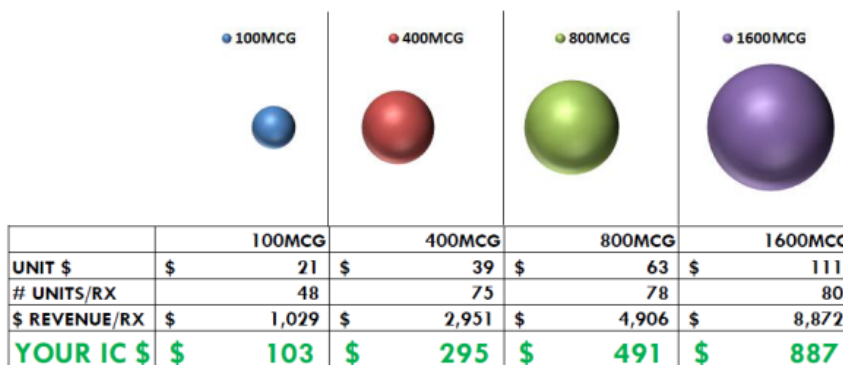
- ✓ Activate new SUBSYS writers
- ✓ Convert more Fentora/Actiq patients to SUBSYS for your existing dr

131. Another slide from that PowerPoint demonstrated how much more sales employees could earn in incentive-based compensation from higher doses. The slide asks, “[i]magine how your payout will differ if your dr writes a single script in either 100, 400, 800 or 1600MCG.” The PowerPoint also included a chart demonstrating how much more “IC” (incentive compensation) could be earned by generating high-strength prescriptions:

Higher \$\$\$/RX: Drive Greater Strength Usage



Imagine how your payout will differ if your dr writes a single script in either 100, 400, 800 or 1600MCG



*: On average the higher the strength, the bigger number of units in a script (WK data).

*: \$ Revenue/RX = (Unit \$) x (# Units/RX)

*: IC payout numbers assumes all are net sales

132. Other slides demonstrated how much more a sales employee could earn by increasing the size of each prescription in terms of units, by generating higher net sales, and by increasing the market share for Subsys. The final slide in the PowerPoint explains how sales employees with the highest market share will be added to the “president’s club.”

133. Correspondence from Insys’s management suggests that sales employees were being trained accordingly, including being told to keep track of dosages and units prescribed. For example, on or about August 8, 2012, the Mid-Atlantic Regional Sales Manager emailed several sales representatives, copying Babich, about sales “success stories” and increasing business. She told those sales

1 employees to check prescription counts daily, reminding them that “it is important
2 that you know who is writing, what dose they are writing, and how many units they
3 are writing.” She reiterated that “to grow your business” the sales employees should,
4 among other things, “gain new writers,” “target higher deciles,” and “go for high
5 dose switches.”
6

7
8 134. Correspondence from Insys sales representatives also suggests that the
9 strategy was being utilized with providers. For example, on or about September 7,
10 2012, an Insys sales representative emailed the Mid-Atlantic Regional Sales
11 Manager (and later forwarded her email to Babich) to summarize her meetings and
12 conversations with providers. Recalling her meeting with one doctor, the sales
13 employee noted that “I asked for his input and feedback on the higher doses if he
14 uses a 1200 or 1600mcg dose bc I think he has the potential to write the higher doses
15 and I think he will.” She also notes that “I will try to see [the doctor] early next
16 week for a more detailed call and effective dosing conversation.”
17
18

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20 135. In that same email on or about September 7, 2012, the Insys sales
21 representative described a meeting with a different doctor. After describing prior
22 meetings with that doctor and her efforts to convert that doctor’s patients from
23 Fentora to Subsys, she continued:
24

25 He told me that he’d just written an 800mcg RX! Whoohoo! ... I talked
26 with [the doctor] regarding...the usual rejection on PA unless the pt
27 meets the indication. I also walked [the doctor] through the PA
28 assistance program and the benefits of it. He found that information

1 very beneficial. We also discussed the quantity of doses RX'd and
2 encouraged him to go ahead and write the higher quantities for the pts
3 who have established a successful dose. ... I also talked with [the
4 doctor's] nurse, and [the doctor's] receptionist, regarding the PA
5 assistance program and the reversed RX's. I took them some
6 nice chocolates which they greatly appreciated.

7 136. On or about October 31, 2012, another Insys sales representative
8 emailed Rowan and described the results of a speaker program involving several
9 providers in her territory. The doctor and physician assistant that participated in the
10 speaker program was associated with a pain management office and not an
11 oncology-related practice. The email also highlights the importance of "ROI" from
12 speaker programs. The sales employee's email stated:

13
14 I just saw yesterday's prescriptions. Talk about ROI- lunch speaker
15 program with [physician assistant] and [doctor] yesterday. [The doctor]
16 wrote his first script of SUBSYS yesterday! Same day! Wow! He is
17 a ROO [rapid onset opioid] decile 1. Fentora decile 2. Like many
18 physicians in SC, awareness in the need of a ROO in their clinical
19 practice for the appropriate patient, agreement that SUBSYS is best in
20 class, and willingness to gain their own clinical experience with the
21 patients in their practice is my goal. This is a big move in the right
22 direction! Yay! I thought you'd like to know :)

23 Furthermore, attached to that email was a detailed spreadsheet tracking Subsys
24 prescriptions from approximately March 1, 2012 to December 1, 2012, including
25 prescriber name, prescription number, pharmacy name, quantity dispensed, sales
26 territory, and assigned sales employee.

27 137. Beginning in or about January of 2013, in advance of numerous speaker
28 programs, Insys sent program confirmation emails to speakers with "approved

1 presentation slides” attached. The “approved presentation slides” was a PowerPoint
2 presentation with 27 pages of slides about Subsys. Despite the approved labeling
3 for Subsys, one of the slides stated that “74% of patients found an effective dose of
4 600 mcg or higher” and that “[o]nly 4% of patients found an effective dose of 100
5 mcg.” The presentation makes no mention of the FDA-approved starting dose of
6 100 mcg.
7
8

9 138. Beginning in or about June of 2013, in advance of numerous speaker
10 programs, Insys sent program confirmation emails to speakers with “approved
11 presentation slides,” and “supplemental slides” attached. The revised “approved
12 presentation slides” was a PowerPoint presentation with 29 pages of slides about
13 Subsys. One of the slides stated that “3 out of 4 patients found an effective SUBSYS
14 dose between 600 – 1600 mcg” and that “[o]nly 4% of patients found an effective
15 dose of 100 mcg.” Again, the presentation makes no mention of the FDA-approved
16 starting dose of 100 mcg. The “supplemental slides” document was a three-page
17 PowerPoint presentation about the prior authorization (“PA”) process and how Insys
18 could “assist with logistics throughout the PA process – all the [sic] up to and
19 including external review.”
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21
22
23

24 F. Insys Focused on Off-Label Marketing and Sales of Subsys

25 139. Insys’s marketing tactics for Subsys substantially focused on strategies
26 to avoid the limiting burdens set forth by the FDA. Insys and its sales representatives
27
28

1 encouraged providers to prescribe Subsys for off-label uses beyond the limited
2 indication for which it was approved (i.e., adult cancer patients experiencing
3 breakthrough cancer pain who are already tolerant to opioid therapy). The FDA-
4 imposed restrictions on Subys limit both who should be prescribed Subsys and who
5 should do the prescribing. Subsys's label states, "Subsys is intended to be used only
6 in the care of cancer patients and only by oncologists and pain specialists who are
7 knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain."
8
9 Insys's ultimate goal was to convince providers to prescribe Subsys for any and all
10 pain, regardless of whether their patients had an underlying cancer diagnoses, and
11 regardless of whether their pain was in fact caused by cancer if actually present.³⁰

14 140. Insys directed its sales representatives to target providers who did not
15 specialize in treating cancer because Insys's managers and directors understood that
16 oncologists were not high volume prescribers. Instead, Insys sales representatives
17 were trained to target practitioners who prescribed TIRF medicines not only for
18 breakthrough cancer pain, but for all pain. Insys executives not only encouraged, but
19 also explicitly instructed their sales force to convince practitioners that Subsys
20 should be used to treat all pain. To illustrate, at a national sales meeting, in or about
21 2014, an Insys executive told Insys sales personnel:

27 ³⁰ *USA v. Kapoor et al.*, 16-cr-10343 (D. Mass.), Indict. ¶¶ 77-81.

1 [t]hese [doctors] will tell you all the time, well, I've only got like eight
2 patients with cancer. Or, I only have, like, twelve patients that are on a
3 rapid-onset opioids [sic]. Doc, I'm not talking about any of those
4 patients. I don't want any of those patients. That's, that's small
5 potatoes. That's nothing. That's not what I'm here doing. I'm here
6 selling [unintelligible] for the breakthrough pain. If I can successfully
7 sell you the [unintelligible] for the breakthrough pain, do you have a
8 thousand people in your practice, a thousand patients, twelve of them
9 are currently on a rapid-onset opioids [sic]. That leaves me with at least
10 five hundred patients that can go on this drug.³¹

11 141. On another occasion, an Insys executive sent a text message to a sales
12 representative that made it clear that Insys expected providers enrolled in the
13 Speaker Program to promote Subsys for the treatment of all pain and not only for
14 breakthrough cancer pain. He stated:

15 I need confirmation from YOU that you had a conversation with... [the
16 practitioner] where he will not ONLY promote for cancer patients. If
17 he does this he will single handedly take down the whole company. He
18 MUST creatively share how docs write this product everywhere. Please
19 get back to me ASAP with confirmation that he will share with our
20 other speakers how effective ... [the Fentanyl Spray] will be to treat
21 ALL BTP [Breakthrough Pain].³²

22 142. In another instance, a Minnesota sales representative advised her
23 supervisor: "Alec [Burlakoff] has been encouraging me to keep looking for my Dr.
24 in Minneapolis, and suggested I go to family practice, internal medicine, or
25 anesthesiologists[.]" In a document titled "Territory Action Plan," the sales
26

27 ³¹ *USA v. Kapoor et al.*, 16-cr-10343 (D. Mass.), Indict. ¶ 80.

28 ³² *Id.* at ¶ 79.

1 representative described her top targets as pain management and primary care
2 doctors.³³

3
4 143. As another example, Dr. A.B., a North Carolina doctor of osteopathic
5 medicine specializing in pain medicine, wrote over \$984,000 in off-label Subsys
6 prescriptions to Patient M.B.,³⁴ who did not have a cancer diagnosis.

7
8 144. Dr. A.U., a North Carolina doctor of osteopathic medicine, wrote over
9 \$495,000 in off-label Subsys prescriptions to Patient M.B., who did not have a
10 cancer diagnosis.

11
12 145. In addition to targeting non-oncology providers and patients for the
13 promotion of Subsys, Insys specifically focused its effort on those providers known
14 to have the reputation for running “pill mills.” One such provider was a physician
15 who is a pain management specialist practicing in Illinois and Indiana, Dr. Paul
16 Madison (hereinafter “Dr. Madison”). On or about September 17, 2012, a sales
17 representative located in the Chicago area sent an email to Babich about her efforts
18 to get Dr. Madison to write Subsys prescriptions:
19
20

21 I call on . . . [him] once sometimes twice a week. . . . [He] runs a very
22 shady pill mill and only accepts cash. He sees very few insured patients
23 but does write some . . . [prescriptions for a competitor product]. He is
24 extremely moody, lazy and inattentive. He basically shows up to sign
his name on the prescription pad, if he shows up at all. I have been

25 ³³ *State of Minnesota v. Insys Therapeutics, Inc.*, 27-CV-18-9081, Compl. ¶ 56.

26 ³⁴ Patient identities are not provided to protect patient privacy and confidential health information.
27 Upon entry of an appropriate protective order, the State of North Carolina will provide Defendant
28 Insys with a list identifying the names of the patients identified herein and details regarding the
claims submitted to the North Carolina Medicaid program for those patients.

1 working more with his MA [“Medical Assistant”] who is the one that
2 knows what is going on in his office. He has agreed to try and help me
3 out but I know that he is afraid of [the doctor’s]...outbursts and is
4 reluctant to input. I think that being in the office at the right time, when
5 the right patient walks in, on a day [the doctor]...is in a good mood is
6 the only way I will get him to write. This is the reason I call on him
7 frequently.³⁵

8 146. Shortly after Insys executives were advised that the Dr. Madison runs
9 a “pill mill”, Sunrise Lee and the sales representative arranged a lunch with him.
10 Following lunch Sunrise Lee gave the practitioner her contact information telling
11 him to call if he wanted to discuss Subsys “in private.” Thereafter in October 2012,
12 Lee and Dr. Madison met for drinks at a popular rooftop bar in downtown Chicago.
13 After this meeting, Dr. Madison [said] that he would start writing Subsys
14 prescriptions – a drug for which he had never previously written prescriptions. By
15 November 2012, the practitioner began participating in Insys’s speaker program and
16 averaged approximately two (2) Subsys prescriptions per week. Dr. Madison’s
17 continued participation in the Insys speaker program ensured the continued increase
18 in the Subsys prescriptions he wrote. By January 2013, he averaged approximately
19 3.6 Subsys prescriptions each week. And the sharpest increase in the frequency of
20 Subsys prescriptions occurred in May 2014, when he was averaging 10.3 Subsys
21 prescriptions each week. During the period between 2013 and 2015, Dr. Madison
22 received roughly \$86,442 in payments from Insys and wrote ninety-two
23
24
25
26

27 ³⁵ *USA v. Kapoor et al.*, 16-cr-10343 (D. Mass.), Indict. ¶ 191.
28

1 prescriptions for six different Indiana Medicaid patients, none of whom had cancer
2 diagnoses. In total, Dr. Madison caused false or fraudulent claims to be submitted
3 to and paid by Indiana Medicaid in the amount of \$909,485.68.³⁶
4

5 G. Insys Lied to Insurers to Persuade Them to Approve Subsys
6 Prescriptions
7

8 147. To increase Subsys sales, Insys developed the Insys Reimbursement
9 Center (commonly known as the “IRC” or “RC”), an internal unit designed to assist
10 doctors and patients with obtaining prior authorizations for Subsys. The IRC would
11 receive patient opt-in forms and utilize these forms to obtain authorization for
12 Subsys from insurers. During this process, IRC employees lied or otherwise misled
13 insurers, including the Medicaid programs of the Intervening States, to obtain
14 reimbursement approval for Subsys.
15
16

17 148. The following paragraphs illustrate Insys’s efforts to facilitate Subsys
18 prescriptions for off-label uses, including in high doses and for non-cancer patients,
19 by making false and/or misleading representations to persuade insurers to approve
20 Subsys prescriptions. These examples are not intended to be a comprehensive or
21 complete list. The Intervening States specifically incorporate by reference
22 Paragraphs 147 through 151 of the Complaint in Intervention of the United States.
23
24
25
26

27 ³⁶ *USA v. Kapoor et al.*, 16-cr-10343 (D. Mass.), Indict. ¶¶ 192-199.
28

1 149. Insys employees and prescribers falsified information and fabricated
2 patient diagnoses in order to receive prior authorizations for Subsys. Furthermore,
3 Insys employees attempted to conceal the identity of their employer by claiming to
4 be calling from providers' offices so as to create the appearance that the provider
5 was the one initiating the prior authorization. The amount of Subsys prescriptions
6 awaiting prior authorization approval became so high at one point that it caused Insys
7 to start losing profits. Insys's solution was to create an IRC in or around January
8 2013, whereby Insys employees would work with the offices of high volume
9 prescribers to assist with and expedite the prior authorization process for Subsys
10 prescriptions. IRC employees were located in Arizona, which is where Insys
11 headquarters are located, and given access to patient's private medical information
12 from prescribing practitioners to carry out their duties.³⁷

13 150. Insys trained IRC employees on strategies to call insurers and PBMs to
14 obtain prior approvals for Subsys. The IRC employees would claim to be calling
15 from the provider's office to create the appearance that they were employed there,
16 however, they were actually employed and compensated by Insys. When asked, the
17 IRC employees would indicate that a patient had a cancer diagnosis with
18 breakthrough pain. A substantial number of patients did not have an underlying
19 cancer diagnosis necessary for prior authorization approval.

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27 ³⁷ *USA v. Kapoor et al.*, 16-cr-10343 (D. Mass.), Indict. ¶¶ 105, 154.

151. Two Insys executives instructed IRC employees to tell insurers and PBMs that they were calling “from”, and “on behalf of”, a provider’s office.³⁸ When insurers and PBMs sought the identity of their employer, IRC employees were instructed to hang up and call back later in hopes of speaking with a less inquisitive individual. Insys provided this instruction to avoid situations like the following exchange that took place on November 14, 2014. On that date, Allison Erickson³⁹ (“Erickson”), who worked as a clinical review regulatory pharmacist for a PBM at the time, received a phone call from “Alyssa” who stated she was calling from a beneficiary’s doctor’s office to obtain prior authorization for a Subsys prescription. Alyssa repeatedly insisted that she was calling from the doctor’s office after several questions from Erickson to confirm Alyssa’s physical location. When Erickson asked Alyssa if she was employed by Insys, Erickson was put on hold and transferred to Alyssa’s supervisor, “Afryea.” After being told that Alyssa was misrepresenting herself as working for the beneficiary’s doctor’s office, Afryea told Erickson that doctors signed business associate agreements with Insys allowing them to make prior authorization requests. Erickson informed Afryea that only a beneficiary, beneficiary’s representative, or a prescriber may initiate a prior authorization

³⁸ *USA v. Kapoor et al.*, 16-cr-10343 (D. Mass.), Indict. ¶ 105.

³⁹ Allison Erickson is a relator in the matter of *United States ex rel. Erickson and Lueken v. Insys Therapeutics, Inc.*, 16-CV-2956 JLS (AJWx)(C.D. Cal.) which has been consolidated. See footnote 2.

1 request. Erickson pressed further. She told Afryea that Insys employees seemed to
2 be providing false patient information to gain approval for Subsys. Afryea refused
3 to answer any questions regarding false patient information given by Insys
4 employees, as well as any questions concerning how IRC employees were
5 compensated.⁴⁰

7
8 152. Erickson noticed a pattern of Insys employees calling in prior
9 authorizations for Subsys and claiming to be calling from a beneficiary's doctor's
10 office. Erickson audited a number of prior authorization requests for Subsys from
11 individuals who made this claim. The results revealed Insys employees initiated
12 prior authorization requests for Subsys for twelve (12) beneficiaries; claimed they
13 were calling from the beneficiary's doctor's office when they were not; and
14 fabricated cancer diagnoses when none was present. Erickson reached out to the
15 beneficiaries' provider offices, and at times, the beneficiaries themselves, to inquire
16 about the presence of a cancer diagnosis. All either explicitly denied the presence
17 of a cancer diagnosis or could not confirm whether a cancer diagnosis was present
18 or not.⁴¹

22 153. Insys executives provided IRC employees with a script to mislead
23 insurers and PBMs regarding the presence of a cancer diagnosis. The script read:
24
25

26 ⁴⁰ *United States ex rel. Erickson and Lueken v. Insys Therapeutics, Inc.*, 16-cv-2956 (C.D Cal.),
27 Compl. ¶ 116.

28 ⁴¹ *Id.* at ¶¶ 116-136.

1 “The physician is aware that the medication is intended for the management of
2 breakthrough pain in cancer patients. The physician is treating the patient for their
3 pain (or breakthrough pain, whichever is applicable).”⁴² The script was consciously
4 designed to avoid using the phrase “breakthrough cancer pain” when describing
5 what the provider intended to treat using Subsys.⁴³
6

7
8 154. Had the insurers and PBMs known the patients did not have the proper
9 indication for treatment, they would not have granted the prior authorizations for
10 Subsys, nor would they have granted the prior authorization requests had they known
11 that Insys employees were the ones calling them in. The Intervening States and their
12 respective Medicaid programs would not have reimbursed those claims for Subsys,
13 which were granted prior authorization only because Insys provided false
14 information.
15
16

17 155. An investigation of a practitioner in Indiana, Dr. A.M., produced
18 information that further supports the allegations against Insys for providing false
19 information to insurers and PBMs in order to obtain prior approvals for Subsys.
20

21 156. Dr. A.M. used “Sherri H”, an Insys employee with the title of PA [Prior
22 Authorization] Specialist, to handle all the prior authorizations for the office in
23 Indiana. “Sherri H” lived and worked in Arizona, which is where Insys’s
24
25
26

27 ⁴² *USA v. Kapoor et al.*, 16-cr-10343 (D. Mass.), Indict. ¶ 109.

28 ⁴³ *Id.*

1 headquarters are located, and received bonus checks based on volume of
2 prescriptions filled. At least seven (7) of the practitioner's patients were prescribed
3 Subsys and none had cancer diagnoses. One Medicare/Medicaid recipient was
4 prescribed Subsys for pain associated with a motorcycle accident and did not have,
5 nor has ever had, cancer.
6

7
8 157. Dr. E.D. is a pain management doctor who prescribed, or attempted to
9 prescribe, Subsys to Virginia Medicaid patients, including recipients who did not
10 have cancer. For example, Dr. E.D. prescribed Subsys for Patient #VA5. Between
11 approximately April 2015 and May 2016, Dr. E.D. wrote Subsys prescriptions for
12 Patient #VA5 and Virginia Medicaid paid 11 claims for more than \$200,000 for
13 Patient #VA5's Subsys.
14

15
16 158. Dr. E.D. started Patient #VA5 on an 800 mcg dose, well above the
17 FDA-approved starting dosage of 100 mcg. Subsys used an IRC employee in
18 Arizona, D.R., to obtain approval from the Virginia Medicaid Program for the
19 prescriptions that Dr. E.D. wrote for Patient #VA5. D.R. contacted the Virginia
20 Medicaid Program numerous times to obtain Subsys approval for Patient #VA5 even
21 though Insys's internal documentation indicated that this patient did not have cancer
22 and was prescribed a starting dose well above the FDA-approved starting dose.
23
24

25 159. On numerous occasions, Insys's IRC employees either lied about a
26 patient's medical history or misled the Virginia Medicaid Program concerning a
27
28

1 patient's medical history to obtain approval, and therefore payment, for Subsys
2 prescriptions. Among other things, IRC employees used false or inaccurate "tried
3 and failed" medication lists to obtain authorization for Subsys. This includes, but it
4 not necessarily limited to, the "tried and failed" medications that the IRC used to
5 request authorization for Subsys for Patient #VA1, Patient #VA2, Patient #VA5, and
6 Patient #VA6.
7
8

9 160. Furthermore, Insys hid the identities of their IRC employees from the
10 Virginia Medicaid Program and suggested that the IRC employees actually worked
11 for the medical practices of the providers who prescribed the medication. For
12 example, in October of 2015, a facsimile cover sheet related to Patient #VA7 states
13 that it is "from" the provider's office and lists the sender "Kisha H." as an "Appeals
14 Specialist," but "Kisha H." is in fact an Insys IRC employee. Insys notes from one
15 of D.R.'s calls to Virginia Medicaid in November of 2015 regarding Patient #VA5
16 states "unblocked the number and asked for clarity if I am calling from the state of
17 Arizona or Virginia...."
18
19
20

21 161. The IRC employees also used buzzwords when talking to the Virginia
22 Medicaid Program regarding patients' need for Subsys to control their
23 "breakthrough pain," slyly omitting the fact that the patients' breakthrough pain is
24 not caused by cancer. For example, the authorization form for Patient #VA5 from
25 February of 2015 stated that Patient #VA5 had "tried & failed other breakthrough
26
27
28

1 medications” and “has an increase in breakthrough pain.” Also, in October of 2015,
2 the IRC attempted to obtain authorization for Subsys for Patient #VA7, despite
3 medical records clearly demonstrating that Patient #VA7 did not have cancer. The
4 prior authorization form stated in two places that Subsys was needed for Patient
5 #VA7’s “breakthrough pain,” subtly omitting “cancer.”
6

7
8 **VIII. CLAIMS OF THE INTERVENING STATES**

9 **A. CLAIMS OF THE STATE OF CALIFORNIA**

10 **COUNT I**

11 **California False Claims Act**

12 **Cal. Gov’t Code § 12651(a)(2) – Use of False Statements or Records Material to a
13 False Claim**

14 162. The allegations in all of the preceding paragraphs are incorporated by
15 reference as if fully set forth herein.

16 163. Throughout the relevant time period, Insys “knowingly” (as defined in
17 Cal. Gov’t. Code § 12650(b)(2)) made, used, or “caused” (as defined in Cal. Gov’t.
18 Code § 12651) to be used, false records or statements material to claims for payment
19 by California, by marketing Subsys for other than FDA-approved uses, lying to
20 insurers including California’s Medicaid program (“Medi-Cal”) about patients’
21 medical conditions to obtain prior authorizations for Subsys prescriptions, and
22 engaging in other conduct as described above, in violation of Cal. Gov’t Code §
23 12650(a)(2).
24
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COUNT II

California False Claims Act

**Cal. Gov't Code § 12651(a)(2) – Causing False Claims to be Presented;
Illegal Remuneration**

164. The allegations in all of the preceding paragraphs are incorporated by reference as if fully set forth herein.

165. Throughout the relevant time period, Insys knowingly offered or paid, or caused to be offered or paid, directly or indirectly, overtly or covertly, in cash or in kind, remuneration to their customers in the form of speaker fees, employment opportunities, paid entertainment, and/or in the form of other illegal remuneration to induce them to purchase, order, or arrange, or to recommend purchasing, arranging, or ordering Subsys, for which Insys knew that payment would be made, in whole or in part, by Medi-Cal. Insys knew Medi-Cal would not have paid or approved claims, if Medi-Cal was made aware of the alleged remuneration, which was in violation of Cal. Welf. & Inst. Code § 14107.2.

COUNT III

California False Claims Act

Cal. Gov't Code § 12651(a)(1) – Causing False Claims to be Presented

166. The allegations in all of the preceding paragraphs are incorporated by reference as if fully set forth herein.

167. Throughout the relevant time period, Insys knowingly presented, or caused to be presented, fraudulent or false claims for payment or approval by Medi-Cal, by targeting prescribers other than those who would otherwise prescribe Subsys

1 for FDA-approved use (i.e., prescribers with no adult cancer patients), incentivizing
2 those providers to prescribe Subsys for other than FDA-approved use, convincing
3 providers to prescribe higher-than-necessary doses of Subsys, and by and engaging
4 in other conduct as described above, in violation of Cal. Gov't Code § 12650(a)(1).

6 **COUNT IV**

7 California False Claims Act

8 Cal. Gov't Code § 12651(a)(3) – Conspiracy; Causing False Claims, or Statements
9 or Records Material to a False Claim, to be Presented

10 168. The allegations in all of the preceding paragraphs are incorporated by
11 reference as if fully set forth herein.

12 169. Throughout the relevant time period, Insys conspired to present, or
13 caused to be presented, fraudulent or false claims or statements or records material
14 to fraudulent or false claims for payment by Medi-Cal, by directing sales
15 representatives to engage in conduct as described above, in violation of Cal. Gov't
16 Code § 12650(a)(3).
17
18

19 **B. CLAIMS OF THE STATE OF COLORADO**

20 **COUNT V**

21 Colorado False Claims Act

22 C.R.S. § 25.5-4-305 (1)(a)
23

24 170. The allegations in all of the preceding paragraphs are incorporated by
25 reference as if fully set forth herein.
26
27
28

1 171. Colo. Rev. Stat. § 25.5-4-305 (1)(a) prohibits knowingly presenting or
2 causing to be presented to an officer or employee of the State of Colorado a false or
3 fraudulent claim for approval, and knowingly making, using, or causing to be made
4 or used a false record or statement material to a false or fraudulent claim under the
5 Colorado Medical Assistance Act, Colo. Rev. Stat. § 25.5-4-101 et seq.
6

7 172. Insys offered and paid kickbacks to prescribers and other health care
8 providers in violation of 42 U.S.C. 1320a-7b(b) and Colorado law and regulations.
9 As a result of these kickbacks, along with Insys's false and fraudulent statements,
10 misrepresentations, and omissions, health care providers submitted, or caused to be
11 submitted, to the State of Colorado and to officers, employees, and agents of the
12 State of Colorado, false claims for payment or approval under the State of
13 Colorado's Medicaid program.
14

15 173. Insys knowingly presented or caused to be presented false and
16 fraudulent claims to the State of Colorado and its officers, employees, and agents.
17 Insys presented or caused to be presented, false or fraudulent claims with actual
18 knowledge of their falsity and fraudulent nature, with deliberate ignorance of the
19 truth or falsity of such claims and information regarding such claims, or with
20 reckless disregard of the truth or falsity of such claims and information.
21

22 174. The false and fraudulent statements and omissions of fact in the claims
23 that Insys caused to be submitted to the State of Colorado and its officers, employees,
24
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1 and agents were material to the State of Colorado's decision to pay the providers
2 submitting such claims, and the State of Colorado would not have paid such claims
3 had it known of Insys's false and fraudulent statements and omissions of fact.
4

5 175. As a result of Insys causing providers to submit false and fraudulent
6 claims, the State of Colorado has suffered substantial damages in an amount to be
7 proven at trial, and is entitled to full restitution in the amount of all payments,
8 moneys, and earnings found by the Court to have been received or retained by Insys
9 due to its violation of C.R.S. § 25.5-4-305, and additionally, a penalty of between
10 \$10,967 and \$22,353 for each false claim submitted, and two times the amount of
11 damages sustained by the State of Colorado.
12
13

14 **COUNT VI**

15 Colorado False Claims Act
16 C.R.S. § 25.5-4-305 (1)(b)

17 176. The allegations in all of the preceding paragraphs are incorporated by
18 reference as if fully set forth herein.
19

20 177. By engaging in the foregoing acts and omissions, and by submitting and
21 maintaining false records and statements, Insys knowingly made, used, or caused to
22 be made or used false records or statements material to false or fraudulent claims
23 under the Colorado Medical Assistance Act. As a result of kickbacks paid by Insys,
24 providers purchased, ordered, recommended, or arranged for the purchase or order
25 of Subys that was paid in whole or in part by the Colorado Medicaid Program.
26
27
28

1 178. Colorado Medicaid, unaware of the use, submission and maintenance
2 of false records and statements by Insys, materially relied on the truth of such records
3 and statements and paid for claims that otherwise would not have been allowed or
4 paid.
5

6 179. The false and fraudulent nature of the records and statements
7 underlying the said claims was material to the State of Colorado's decision to pay
8 for the claims, and the State of Colorado would not have paid such claims had it
9 known of such false and fraudulent records and statements.
10

11 180. As a result of Insys's use and submission of false and fraudulent records
12 and statements, the State of Colorado has suffered substantial damages in an amount
13 to be proven at trial, and is entitled to full restitution in the amount of all payments,
14 moneys, and earnings found by the Court to have been received or retained by Insys
15 due to its violation of C.R.S. § 25.5-4-305, and additionally, a penalty of between
16 \$10,967 and \$22,353 for each false claim submitted, and two times the amount of
17 damages sustained by the State of Colorado.
18
19
20

21 **COUNT VII**
22 **Unjust Enrichment**

23 181. The allegations in all of the preceding paragraphs are incorporated by
24 reference as if fully set forth herein.
25

26 182. Insys caused the submission of claims to Colorado Medicaid that were
27 not payable or allowable under Colorado statutory and regulatory law.
28

1 183. The State of Colorado Medicaid Program paid substantially more
2 money than it would have had Insys not caused the submission of such false claims,
3 or had Colorado Medicaid known that such claims were false. The payment of
4 money by the State of Colorado Medicaid Program benefited Insys because Insys
5 was in turn paid for drugs that had been paid for by the State of Colorado's Medicaid
6 Program.
7

8
9 184. By retaining monies that were paid under the premises described above,
10 and failing to return the same, Insys has retained money that is the property of the
11 State of Colorado and to which it is not entitled.
12

13 185. Insys has been unjustly enriched by retaining the use and enjoyment of
14 the monies that should have been kept by the State of Colorado.
15

16 186. Insys is liable to the State of Colorado in equity for the return of all
17 moneys retained by Insys in these premises, plus pre- and post-judgment interest.
18

19 **C. CLAIMS OF THE STATE OF INDIANA**

20 **COUNT VIII**

21 Indiana False Claims and Whistleblower Protection Act
22 Ind. Code § 5-11-5.5-2(b)(2)

23 187. The allegations in all of the preceding paragraphs are incorporated by
24 reference as if fully set forth herein.

25 188. The Indiana False Claims and Whistleblower Protection Act ("IFCA")
26 provides, in pertinent part, a person who knowingly or intentionally:
27
28

1 (2) makes or uses a false record or statement to obtain payment or
2 approval of a false claim from the state;

3 ***

4 is,...liable to the state for a civil penalty of at least five thousand dollars
5 (\$5,000) and for up to three (3) times the amount of damages sustained
6 by the state. In addition, a person who violates this section is liable to
7 the state for the costs of a civil action brought to recover a penalty or
8 damages.

9 Ind. Code § 5-11-5.5-2(b).

10 189. Beginning in or about May 2012 and continuing until June 30, 2013,
11 Insys knowingly caused the Indiana Health Coverage Programs, the single state
12 agency designated to administer the Medicaid program in the State of Indiana under
13 Title XIX of the Social Security Act, and its vendors, agents, and contractors
14 (collectively, "IHCP") to pay for Subsys for uses for which it was not approved.
15 Insys did this by, among other things, misrepresenting patients' medical diagnoses
16 to the IHCP or their Pharmacy Benefits Managers in order to obtain reimbursement
17 for Subsys.
18

19
20 190. Insys's false and fraudulent statements, representations, or records were
21 made or used to obtain approval and payment of false claims for Subsys that were
22 submitted to the IHCP and were material the payment of false claims to the IHCP.
23

24 191. As a result of the false or fraudulent statements, representations, or
25 records made or used by Insys obtain approval and payment of false claims for
26 Subsys that were submitted to the IHCP, Insys is liable to the State of Indiana for
27
28

1 civil penalties of not less than \$5,500, plus three times the amount of actual damages
2 that the State of Indiana sustained because of Insys's wrongful conduct, along with
3 the costs of a civil action brought to recover a penalty or damages.
4

5 **COUNT IX**

6 Indiana False Claims and Whistleblower Protection Act
7 Ind. Code § 5-11-5.5-2(b)(7)

8 192. The allegations in all of the preceding paragraphs are incorporated by
9 reference as if fully set forth herein.

10 193. The IFCA provides, in pertinent part, a person who knowingly or
11 intentionally:
12

13 (2) makes or uses a false record or statement to obtain payment or
14 approval of a false claim from the state;

15 ***

16 (7) conspires with another person to perform an act described in
17 subdivisions (1) through (6)

18 ***

19 is,...liable to the state for a civil penalty of at least five thousand dollars
20 (\$5,000) and for up to three (3) times the amount of damages sustained
21 by the state. In addition, a person who violates this section is liable to
22 the state for the costs of a civil action brought to recover a penalty or
23 damages.

24 Ind. Code § 5-11-5.5-2(b).

25 194. Beginning in or about May 2012 and continuing until June 30, 2013,
26 Insys knowingly caused the IHCP to pay for Subsys for uses for which it was not
27
28

1 approved. Insys did this by, among other things, conspiring with others to
2 misrepresent patients' medical diagnoses to the IHCP or their Pharmacy Benefits
3 Managers in order to obtain reimbursement for Subsys.
4

5 195. The false and fraudulent statements, representations, or records made
6 by Insys or its co-conspirators were made or used to obtain approval and payment
7 of false claims for Subsys that were submitted to the IHCP and were material the
8 payment of false claims to the IHCP.
9

10 196. As a result of the false or fraudulent statements, representations, or
11 records made or used by Insys or its co-conspirators to obtain approval and payment
12 of false claims for Subsys that were submitted to the IHCP, Insys is liable to the
13 State of Indiana for civil penalties of not less than \$5,500, plus three times the
14 amount of actual damages that the State of Indiana sustained because of Insys's
15 wrongful conduct, along with the costs of a civil action brought to recover a penalty
16 or damages.
17
18
19

20 **COUNT X**

21 Indiana False Claims and Whistleblower Protection Act
22 Ind. Code § 5-11-5.5-2(b)(8)

23 197. The allegations in all of the preceding paragraphs are incorporated by
24 reference as if fully set forth herein.

25 198. The IFCA provides, in pertinent part, a person who knowingly or
26 intentionally:
27
28

1 (1) presents a false claim to the state for payment or approval;
2 (2) makes or uses a false record or statement to obtain payment or
3 approval of a false claim from the state;

4 ***

5 (8) causes or induces another person to perform an act described in
6 subdivisions (1) through (6)

7 ***

8 is,...liable to the state for a civil penalty of at least five thousand dollars
9 (\$5,000) and for up to three (3) times the amount of damages sustained
10 by the state. In addition, a person who violates this section is liable to
11 the state for the costs of a civil action brought to recover a penalty or
12 damages.

13 Ind. Code § 5-11-5.5-2(b).

14 199. Beginning in or about May 2012 and continuing until June 30, 2013,
15 Insys has knowingly offered and paid kickbacks to induce physicians and nurse
16 practitioners to prescribe Subsys for their patients. Additionally, Insys knowingly
17 caused the IHCP to pay for Subsys for uses for which it was not approved. Insys did
18 this by, among other things, (1) encouraging prescribers to prescribe Subsys in
19 situations where it was not medically reasonable and necessary based on patients'
20 medical conditions (i.e., because a patient did not have cancer), and (2)
21 misrepresenting patients' medical diagnoses to the IHCP or their Pharmacy Benefits
22 Managers in order to obtain reimbursement for Subsys.
23
24

25 200. As a result of kickbacks paid by Insys, providers purchased, ordered,
26 recommended or arranged for the purchase or order of Subsys that was paid for in
27
28

1 whole or in part by the IHCP, in violation of the federal anti-kickback statute, 42
2 U.S.C. § 1320a-7b(b), and Indiana's anti-kickback statute, Ind. Code § 12-15-24-2.

3
4 201. Insys's knowing and willful false statements, misrepresentations, and
5 fraudulent scheme caused providers and pharmacies in the State of Indiana to submit
6 claims to the IHCP for reimbursement based on false, fraudulent, and misleading
7 information. As a result, Insys caused false and fraudulent claims to be submitted
8 to the IHCP and Insys's conduct directly resulted in a significant financial loss to the
9 IHCP.
10

11
12 202. As a result of the kickbacks, the false or fraudulent statements,
13 representations, or records made or used by Insys to obtain approval and payment of
14 false claims, Insys caused false claims to be presented or submitted to the IHCP and
15 Insys is liable to the State of Indiana for civil penalties of not less than \$5,500, plus
16 three times the amount of actual damages that the State of Indiana sustained because
17 of Insys's wrongful conduct, along with the costs of a civil action brought to recover
18 a penalty or damages.
19
20

21 **COUNT XI**

22 **Indiana Medicaid False Claims and Whistleblower Protection Act**
23 **Ind. Code § 5-11-5.7-2(a)(1)**

24 203. The allegations in all of the preceding paragraphs are incorporated by
25 reference as if fully set forth herein.
26
27
28

1 204. The Indiana Medicaid False Claims and Whistleblower Protection Act
2 (“IMFCA”) provides, in pertinent part, a person who:

3 (1) knowingly presents, or causes to be presented, a false or fraudulent
4 claim for payment or approval;

5 ***

6
7 is ... liable to the state for a civil penalty of at least five thousand five
8 hundred dollars (\$5,500) and not more than eleven thousand dollars
9 (\$11,000), as adjusted by the federal Civil Penalties Inflation
10 Adjustment Act of 1990 (28 U.S.C. 2461 note, Public Law 101-410),
11 and for up to three (3) times the amount of damages sustained by the
12 state. In addition, a person who violates this section is liable to the state
13 for the costs of a civil action brought to recover a penalty or damages.

14 Ind. Code § 5-11-5.7-2(a).

15 205. Beginning on or about July 1, 2013 and continuing until the present
16 Insys has knowingly offered and paid kickbacks to induce physicians and nurse
17 practitioners to prescribe Subsys for their patients. Additionally, Insys knowingly
18 caused the IHCP to pay for Subsys for uses for which it was not approved. Insys did
19 this by, among other things, (1) encouraging prescribers to prescribe Subsys in
20 situations where it was not medically reasonable and necessary based on patients’
21 medical conditions (i.e., because a patient did not have cancer), and (2)
22 misrepresenting patients’ medical diagnoses to the IHCP or their Pharmacy Benefits
23 Managers in order to obtain reimbursement for Subsys.
24

25 206. As a result of the kickbacks paid by Defendant Insys, providers
26 purchased, ordered, recommended or arranged for the purchase or order of Subsys
27
28

1 that was paid for in whole or in part by the IHCP, in violation of the federal anti-
2 kickback statute, 42 U.S.C. § 1320a-7b(b), and Indiana's anti-kickback statute, Ind.
3 Code § 12-15-24.
4

5 207. The actions of Insys, including the offer and payment of kickbacks and
6 the false and fraudulent statements and representations made by Insys, were material
7 to the payment of claims submitted or caused to be submitted by Insys to Indiana
8 Medicaid.
9

10 208. Insys presented or caused to be presented false or fraudulent claims for
11 payment or approval with actual knowledge of their falsity, with deliberate
12 ignorance as to their truth or falsity, or with reckless disregard as to their truth or
13 falsity.
14

15 209. By virtue of the acts alleged above, Insys knowingly presented, or
16 caused to be presented, false or fraudulent claims for payment or approval to the
17 state of Indiana in violation of Ind. Code § 5-11-5.7-2(a)(1).
18

19 210. As a result of the false or fraudulent claims Insys knowingly presented,
20 or caused to be presented, for payment or approval to the state of Indiana, Insys is
21 liable to the state of Indiana for civil penalties of at least \$5,500 and not more than
22 \$11,000, as adjusted by the federal Civil Penalties Inflation Adjustment Act of 1990
23 (28 U.S.C. 2461 note, Public Law 101-410), plus up to three (3) times the amount
24 of damages sustained by the state of Indiana in addition to the costs of a civil action
25
26
27
28

brought by the state of Indiana to recover the penalty or damages caused by Insys's wrongful conduct.

COUNT XII

**Indiana False Medicaid Claims and Whistleblower Protection Act
Ind. Code § 5-11-5.7-2(a)(2)**

211. The allegations in all of the preceding paragraphs are incorporated by reference as if fully set forth herein.

212. The IMFCA provides, in pertinent part, a person who:

(2) knowingly makes, uses, or causes to be made or used, a false record or statement that is material to a false or fraudulent claim;

is ... liable to the state for a civil penalty of at least five thousand five hundred dollars (\$5,500) and not more than eleven thousand dollars (\$11,000), as adjusted by the federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note, Public Law 101-410), and for up to three (3) times the amount of damages sustained by the state. In addition, a person who violates this section is liable to the state for the costs of a civil action brought to recover a penalty or damages.

Ind. Code § 5-11-5.7-2(a).

213. The actions of Insys, including the false and fraudulent statements and representations made by Insys, were material to the payment of claims submitted or caused to be submitted by Insys to Indiana Medicaid.

214. By virtue of the acts alleged above, Insys knowingly made, used, or caused to be made or used, false records or statements that are material to false or fraudulent claims in violation of Ind. Code § 5-11-5.7-2(a)(2).

215. As a result of the false records or statements that are material to false or fraudulent claims, Insys is liable to the state of Indiana for civil penalties of at least \$5,500 and not more than \$11,000, as adjusted by the federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note, Public Law 101-410), plus up to three (3) times the amount of damages sustained by the state of Indiana in addition to the costs of a civil action brought by the state of Indiana to recover the penalty or damages caused by Insys's wrongful conduct.

COUNT XIII

**Indiana False Medicaid Claims and Whistleblower Protection Act
Ind. Code § 5-11-5.7-2(a)(7)**

216. The allegations in all of the preceding paragraphs are incorporated by reference as if fully set forth herein.

217. The IMFCA provides, in pertinent part, a person who:

- (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
- (2) knowingly makes, uses, or causes to be made or used, a false record or statement that is material to a false or fraudulent claim;

- (7) conspires with another person to perform an act described in subdivisions (1) through (6)

is ... liable to the state for a civil penalty of at least five thousand five hundred dollars (\$5,500) and not more than eleven thousand dollars (\$11,000), as adjusted by the federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note, Public Law 101-410),

1 and for up to three (3) times the amount of damages sustained by the
2 state. In addition, a person who violates this section is liable to the state
3 for the costs of a civil action brought to recover a penalty or damages.

4 Ind. Code § 5-11-5.7-2(a).

5 218. Beginning on or about July 1, 2013 and continuing until the present
6 Insys has knowingly offered and paid kickbacks to induce physicians and nurse
7 practitioners to prescribe Subsys for their patients. Additionally, Insys knowingly
8 caused the IHCP to pay for Subsys for uses for which it was not approved. Insys did
9 this by, among other things, (1) conspiring with prescribers to prescribe Subsys in
10 situations where it was not medically reasonable and necessary based on patients'
11 medical conditions (i.e., because a patient did not have cancer), and (2) conspiring
12 to misrepresent patients' medical diagnoses to the IHCP or their Pharmacy Benefits
13 Managers in order to obtain reimbursement for Subsys.
14
15
16

17 219. As a result of the kickbacks paid by Defendant Insys, providers
18 purchased, ordered, recommended or arranged for the purchase or order of Subsys
19 that was paid for in whole or in part by the IHCP, in violation of the federal anti-
20 kickback statute, 42 U.S.C. § 1320a-7b(b), and Indiana's anti-kickback statute, Ind.
21 Code § 12-15-24.
22
23

24 220. The actions of Insys and its co-conspirators, including the offer and
25 payment of kickbacks and the false and fraudulent statements and representations
26
27
28

1 made by Insys, were material to the payment of claims submitted or caused to be
2 submitted by Insys to Indiana Medicaid.

3
4 221. Insys presented or caused to be presented false or fraudulent claims for
5 payment or approval with actual knowledge of their falsity, with deliberate
6 ignorance as to their truth or falsity, or with reckless disregard as to their truth or
7 falsity.
8

9 222. By virtue of the acts alleged above, Insys and its co-conspirators: (1)
10 knowingly presented, or caused to be presented, false or fraudulent claims for
11 payment or approval in violation of Ind. Code § 5-11-5.7-2(a)(1); or (2) knowingly
12 made, used, or caused to be made or used, false records or statements that are
13 material to false or fraudulent claims in violation of Ind. Code § 5-11-5.7-2(a)(2).
14
15

16 223. As a result of the acts of Insys and its co-conspirators false records or
17 statements that are material to false or fraudulent claims, Insys is liable to the state
18 of Indiana for civil penalties of at least \$5,500 and not more than \$11,000, as
19 adjusted by the federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C.
20 2461 note, Public Law 101-410), plus up to three (3) times the amount of damages
21 sustained by the state of Indiana in addition to the costs of a civil action brought by
22 the state of Indiana to recover the penalty or damages caused by Insys's wrongful
23 conduct.
24
25

26 **COUNT XIV**

27 Indiana False Medicaid Claims and Whistleblower Protection Act
28

Ind. Code § 5-11-5.7-2(a)(8)

224. The allegations in all of the preceding paragraphs are incorporated by reference as if fully set forth herein.

225. The IMFCA provides, in pertinent part, a person who:

(1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement that is material to a false or fraudulent claim;

(8) causes or induces another person to perform an act described in subdivisions (1) through (6)

is ... liable to the state for a civil penalty of at least five thousand five hundred dollars (\$5,500) and not more than eleven thousand dollars (\$11,000), as adjusted by the federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note, Public Law 101-410), and for up to three (3) times the amount of damages sustained by the state. In addition, a person who violates this section is liable to the state for the costs of a civil action brought to recover a penalty or damages.

Ind. Code § 5-11-5.7-2(a).

226. Beginning on or about July 1, 2013 and continuing until the present Insys has knowingly offered and paid kickbacks to induce physicians and nurse practitioners to prescribe Subsys for their patients. Additionally, Insys knowingly caused the IHCP to pay for Subsys for uses for which it was not approved. Insys did this by, among other things, (1) conspiring with prescribers to prescribe Subsys in

1 situations where it was not medically reasonable and necessary based on patients'
2 medical conditions (i.e., because a patient did not have cancer), and (2) conspiring
3 to misrepresent patients' medical diagnoses to the IHCP or their Pharmacy Benefits
4 Managers in order to obtain reimbursement for Subsys.

5
6 227. As a result of the kickbacks paid by Defendant Insys, providers
7 purchased, ordered, recommended or arranged for the purchase or order of Subsys
8 that was paid for in whole or in part by the IHCP, in violation of the federal anti-
9 kickback statute, 42 U.S.C. § 1320a-7b(b), and Indiana's anti-kickback statute, Ind.
10 Code § 12-15-24.
11

12
13 228. The actions of Insys, including the offer and payment of kickbacks and
14 the false and fraudulent statements and representations made by Insys, were material
15 to the payment of claims submitted or caused to be submitted by Insys to Indiana
16 Medicaid.
17

18 229. Insys presented or caused to be presented false or fraudulent claims for
19 payment or approval with actual knowledge of their falsity, with deliberate
20 ignorance as to their truth or falsity, or with reckless disregard as to their truth or
21 falsity.
22

23 230. By virtue of the acts alleged above, Insys: (1) knowingly presented, or
24 caused to be presented, false or fraudulent claims for payment or approval in
25 violation of Ind. Code § 5-11-5.7-2(a)(1); or (2) knowingly made, used, or caused to
26
27
28

1 be made or used, false records or statements that are material to false or fraudulent
2 claims in violation of Ind. Code § 5-11-5.7-2(a)(2).

3
4 231. As a result of the acts of Insys and its co-conspirators false records or
5 statements that are material to false or fraudulent claims, Insys is liable to the state
6 of Indiana for civil penalties of at least \$5,500 and not more than \$11,000, as
7 adjusted by the federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C.
8 2461 note, Public Law 101-410), plus up to three (3) times the amount of damages
9 sustained by the state of Indiana in addition to the costs of a civil action brought by
10 the state of Indiana to recover the penalty or damages caused by Insys's wrongful
11 conduct.
12
13

14 **COUNT XV**

15 Indiana's Anti-Kickback Statute
16 Ind. Code § 12-15-24-1

17 232. The allegations in all of the preceding paragraphs are incorporated by
18 reference as if fully set forth herein.
19

20 233. Indiana's Anti-Kickback Statute ("AKS"), Ind. Code § 12-15-24-2,
21 provides in pertinent part:

22 A person who furnishes items or services to an individual for which
23 payment is or may be made under this chapter and who solicits, offers,
24 or receives a: (1) kickback or bribe in connection with the
25 furnishing of the items or services or the making or receipt of the
26 payment;

27 ***

28 commits a Class A misdemeanor.

1
2 234. Furthermore, Indiana's AKS statute, Ind. Code § 12-15-24-1 provides
3 in pertinent part :

4 Evidence that a person or provider received money or other benefits as
5 a result of a violation of a provision of this article;

6 ***

7 constitutes prima facie evidence, for purposes of IC 35-43-4-2, that the
8 person or provider intended to deprive the state of a part of the value of
9 the money or benefits.

10 Ind. Code § 12-15-24-1.

11 235. As a result of bribes, fraud, and kickbacks paid by Defendant Insys,
12 providers purchased, ordered, recommended or arranged for the purchase or order
13 of Subsys that was paid for in whole or in part by Indiana Medicaid, in violation of
14 the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), and Indiana's anti-
15 kickback statute, Ind. Code § 12-15-24.

16
17 236. Insys offered and executed kickbacks and bribes to providers in
18 exchange for writing Subsys prescriptions in order to allow Insys to receive payment
19 of those prescriptions from Indiana Medicaid.
20

21 237. By virtue of the acts alleged above, Insys furnished items or services to
22 providers for which payment was or may have been made under Ind. Code § 12-15-
23 24 and solicited, offered, or received a kickback or bribe in connection with the
24 furnishing of the items or services or the making or receipt of the payment in
25 violation of Ind. Code § 12-15-24-2.
26
27
28

238. In turn, the resulting violation of Ind. Code § 12-15-24-2(1) constitutes prima facie evidence for purposes of Indiana's theft statute, Ind. Code § 35-43-4-2, that Insys intended to deprive the state of a part of the value of the money or benefits according to Ind. Code § 12-15-24-1(1).

COUNT XVI

Theft

Ind. Code § 35-43-4-2(a)(2)(A)

239. The allegations in all of the preceding paragraphs are incorporated by reference as if fully set forth herein.

240. Indiana's theft statute provides in pertinent part,

(a) A person who knowingly or intentionally exerts unauthorized control over property of another person, with intent to deprive the other person of any part of its value or use, commits theft, a Class A misdemeanor. However, the offense is:

(a)(2)(A) A Level 5 felony if the value of the property is at least fifty thousand dollars (\$50,000)

Ind. Code § 35-43-4-2(a)(2)(A).

241. For the purposes of the theft statute, the phrase "exert control over property" means to obtain, take, carry, drive, lead away, conceal, abandon, sell, convey, encumber, or possess property, or to secure, transfer, or extend a right to property. Ind. Code § 35-43-4-1(a). Furthermore, Ind. Code § 35-43-4-1(b)(1) provides that a person's control over property of another person is "unauthorized" if

1 it is exerted without the other person's consent, or, in a manner or to an extent other
2 than that to which the other person has consented. Pursuant to Ind. Code § 1-1-4-
3 5(a)(17), the term "person" extends to bodies politic and corporate.
4

5 242. As a result of bribes, fraud, and kickbacks paid by Defendant Insys,
6 providers purchased, ordered, recommended or arranged for the purchase or order
7 of Subsys that was paid for in whole or in part by Indiana Medicaid, in violation of
8 the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), and Indiana's anti-
9 kickback statute, Ind. Code § 12-15-24.
10

11 243. The actions of Insys, including the offer and payment of kickbacks and
12 the false and fraudulent statements and representations made by Insys, were material
13 to the payment of claims submitted or caused to be submitted by Insys to Indiana
14 Medicaid. As such, Insys's obtainment and possession of payment from Indiana
15 Medicaid was acquired without the state's consent, or, in a manner or to an extent
16 other than that to which the state consented.
17
18

19 244. Furthermore, and pursuant to Ind. Code § 12-15-24-1(1) detailed above,
20 Insys's violation of Ind. Code § 12-15-24-2(1) constitutes prima facie evidence for
21 purposes of Indiana's theft statute, Ind. Code § 35-43-4-2, that Insys intended to
22 deprive the state of a part of the value of the money or benefits.
23
24

25 245. Therefore, Insys knowingly or intentionally exerted unauthorized
26 control over property of the state of Indiana with intent to deprive the state of its
27
28

1 value by obtaining and possessing payment in excess of \$50,000 for false or
2 fraudulent claims presented to Indiana Medicaid, which were brought about by
3 Insys's offers and payments of bribes and kickbacks to providers.
4

5 246. By virtue of the acts alleged above, Insys knowingly or intentionally
6 exerted unauthorized control over property of the Indiana Medicaid program, with
7 intent to deprive the Indiana Medicaid program of any part of its value or use in
8 violation of Ind. Code § 35-43-4-2.
9

10 **COUNT XVII**
11 Medicaid Fraud
12 Ind. Code § 35-43-5-7.1

13 247. The allegations in all of the preceding paragraphs are incorporated by
14 reference as if fully set forth herein.
15

16 248. Indiana's Medicaid Fraud statute, Ind. Code § 35-43-5-7.1 provides in
17 pertinent part,
18

19 (1) Except as provided in subsection (b), a person who knowingly or
20 intentionally makes, utters, presents, or causes to be presented to the
21 Medicaid program under IC 12-15 a Medicaid claim that contains
materially false or misleading information concerning the claim;

22 ***

23 Commits Medicaid fraud, a Class A misdemeanor.
24

25 ***

26 The offense described in subsection (a) is:
27

28 ***

1 (2) a Level 5 felony if the fair market value of the offense is at least
2 fifty thousand dollars (\$50,000).
3 Ind. Code § 35-43-5-7.1(a-b).

4 249. As a result of As a result of bribes, fraud, and kickbacks paid by
5 Defendant Insys, providers purchased, ordered, recommended or arranged for the
6 purchase or order of Subsys that was paid for in whole or in part by Indiana
7 Medicaid, in violation of the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b),
8 and Indiana's anti-kickback statute, Ind. Code § 12-15-24.

9
10 250. The actions of Insys, including the offer and payment of kickbacks and
11 the false and fraudulent statements and representations made by Insys, were material
12 to the payment of claims submitted or caused to be submitted by Insys to Indiana
13 Medicaid.

14
15 251. Insys presented or caused to be presented false or fraudulent claims for
16 payment or approval with actual knowledge of their falsity, with deliberate
17 ignorance as to their truth or falsity, or with reckless disregard as to their truth or
18 falsity.

19
20 252. By virtue of the acts alleged above, Insys knowingly or intentionally
21 made, uttered, presented, or caused to be presented to the Medicaid program
22 Medicaid claims that contained materially false or misleading information
23 concerning the claims in violation of Ind. Code § 35-43-5-7.1(a).

1 (5) A reasonable amount to compensate the person suffering loss for
2 time used to:

3 (A) file papers and attend court proceedings related to the
4 recovery of a judgment under this chapter; or

5 (B) travel to and from activities described in clause (A).

6 (6) Actual direct and indirect expenses incurred by the person suffering
7 loss to compensate employees and agents for time used to:

8 (A) file papers and attend court proceedings related to the
9 recovery of a judgment under this chapter; or

10 (B) travel to and from activities described in clause (A).

11 (7) All other reasonable costs of collection.

12 Ind. Code § 34-24-3-1.

13 256. By virtue of the acts alleged above, Insys knowingly or intentionally
14 exerted unauthorized control over property of the Indiana Medicaid program, with
15 intent to deprive the Indiana Medicaid program of any part of its value or use in
16 violation of Ind. Code § 35-43-4-2.

17 257. By virtue of the acts alleged above, Insys knowingly or intentionally
18 made, uttered, presented, or caused to be presented to the Medicaid program
19 Medicaid claims that contained materially false or misleading information
20 concerning the claims in violation of Ind. Code § 35-43-5-7.1(a).

21 258. As a result of Insys's violations of Ind. Code § 35-43-4-2 and Ind. Code
22 § 35-43-5-7.1(a), the State of Indiana has suffered a pecuniary loss and is entitled to
23 the relief described above.

24 **D. CLAIMS OF THE STATE OF MINNESOTA**

25 **COUNT XIX**

26 **Minnesota False Claims Act**

Minn. Stat. § 15C.02(a)

259. The allegations in all of the preceding paragraphs are incorporated by reference as if fully set forth herein.

260. Minnesota Statutes § 15C.02(a) provides, in pertinent part:

A person who commits any act described in clauses (1) to (7) is liable to the state or the political subdivision for a civil penalty of not less than \$5,500 and not more than \$11,000 per false or fraudulent claim, plus three times the amount of damages that the state or political subdivision sustains because of the act of that person . . .

(1) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(2) Knowingly makes or uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(3) Knowingly conspires to commit a violation of clause (1), (2) . . .

261. Insys knowingly presented, or caused to be presented, materially false and fraudulent claims for payment or approval to the Minnesota Medical Assistance (Medicaid) program that were materially false and fraudulent because they were for prescription drugs ordered or prescribed by persons to whom Insys had paid kickbacks in violation of the AKS, were for patients and conditions that were not covered by the Medicaid program, and/or were for inappropriate and unauthorized doses of Subsys. Insys knowingly made or used, or caused to be made or used, false records and statements material to false or fraudulent claims by training and directing its sales representatives to market Subsys for off-label purposes, targeting

1 non-oncology providers, paying kickbacks in the form of speaker program
2 payments, lying to insurers and PBMs about patients' medical conditions to obtain
3 prior authorization, and engaging in other conduct as described above. As detailed
4 in the complaint.
5

6 **COUNT XX**
7 Unjust Enrichment

8 262. The allegations in all of the preceding paragraphs are incorporated by
9 reference as if fully set forth herein.
10

11 263. As a consequence of Insys wrongfully obtaining funds made by
12 Minnesota's Medicaid program, Insys was unjustly enriched at the expense of
13 Minnesota, which, under the circumstances, in equity and good conscience, Insys
14 should not be allowed to retain these funds.
15

16 264. By reason of the unjust enrichment described above, Minnesota is
17 entitled to damages in an amount to be determined at trial.
18

19
20 E. CLAIMS OF THE STATE OF NEW YORK

21 **COUNT XXI**
22 New York False Claims Act
23 N.Y. State Fin. Law § 189(1)(a) and (c)

24 265. The allegations in the preceding paragraphs are incorporated by
25 reference as if fully set forth herein.
26
27
28

1 266. As a result of Insys' kickbacks and offers of kickbacks in violation of
2 the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), 18 N.Y.C.R.R.
3 § 515.2(b), the New York Anti-Kickback Statute, New York Social Services Law
4 § 366-d(2), and the laws, rules and regulations of the New York State Medicaid
5 Program, including its provider manuals, false and fraudulent claims for payment
6 were made to the State of New York. Accordingly, Insys knowingly caused to be
7 presented false or fraudulent claims for payment or approval in violation of N.Y.
8 State Fin. Law § 189(1)(a), or knowingly conspired to do the same in violation of
9 N.Y. State Fin. Law § 189(1)(c).

10
11
12
13 267. By reason of the false or fraudulent claims, the State of New York has
14 sustained damages in a substantial amount to be determined at trial, and is entitled
15 to treble damages plus a civil penalty of \$6,000 to \$12,000 for each violation.
16

17 **COUNT XXII**

18 New York False Claims Act
19 N.Y. State Fin. Law § 189(1)(b) and (c)

20 268. The allegations in all of the preceding paragraphs are incorporated by
21 reference as if fully set forth herein.

22 269. As a result of Insys' kickbacks and offers of kickbacks in violation of
23 the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), 18 N.Y.C.R.R.
24 § 515.2(b), the New York Anti-Kickback Statute, New York Social Services Law
25 § 366-d(2), and the laws, rules and regulations of the New York State Medicaid
26
27
28

1 Program, including its provider manuals, Insys knowingly caused to be made false
2 records or statements or omissions that were material to false or fraudulent claims
3 for payment submitted to the State of New York, in violation of N.Y. State Fin. Law
4 § 189(1)(b), or knowingly conspired to do the same in violation of N.Y. State Fin.
5 Law § 189(1)(c). The false records or statements or omissions were false
6 certifications, representations, or omissions that services were provided in
7 compliance with all applicable Federal and State laws and regulations, including but
8 not limited to the Federal and New York Anti-Kickback regulations and statutes and
9 the laws, rules and regulations of the New York State Medicaid Program, including
10 its provider manuals.
11
12
13

14 270. By reason of the false records or statements, the State of New York has
15 sustained damages in a substantial amount to be determined at trial, and is entitled
16 to treble damages plus a civil penalty of \$6,000 to \$12,000 for each violation.
17

18 **COUNT XXIII**

19 New York Social Services Law § 145-b

20 271. The allegations in all of the preceding paragraphs are incorporated by
21 reference as if fully set forth herein.
22

23 272. As set forth above, Insys knowingly caused to be presented to the State
24 of New York false or fraudulent claims for payment.
25

26 273. The State of New York paid such false or fraudulent claims as a result
27 of the acts of Insys.
28

1 274. By reason of Insys' conduct, the State of New York has been damaged
2 in a substantial amount to be determined at trial.

3 275. By reason of the foregoing, Insys is liable, pursuant to N.Y. Social
4 Services Law § 145-b, to the State of New York for treble damages, penalties, costs,
5 and interest at the highest legal rate.
6

7
8 **COUNT XXIV**

9 Repeated Fraudulent Acts
10 New York Executive Law § 63(12)

11 276. The allegations in all of the preceding paragraphs are incorporated by
12 reference as if fully set forth herein.

13 277. N.Y. Executive Law § 63(12) makes "repeated fraudulent...acts
14 of...persistent fraud...in the carrying on, conducting or transaction of business
15 actionable by the Attorney General."
16

17 278. By engaging in the acts and practices described above, Insys has
18 engaged in repeated fraudulent acts or persistent fraud in violation of N.Y. Executive
19 Law § 63(12).
20

21 279. By reason of the foregoing, Insys is liable to the State of New York for
22 damages, in an amount to be determined at trial, for the economic injuries suffered
23 by the State of New York.
24

25 **COUNT XXV**

26 Misappropriation of Public Property
27 New York Executive Law § 63-c

1 280. The allegations in all of the preceding paragraphs are incorporated by
2 reference as if fully set forth herein.

3 281. The acts and practices of Insys complained of herein constitute a
4 misappropriation of public property, in violation of N.Y. Executive Law § 63-c. By
5 reason of the foregoing, the State of New York is entitled to restitution from Insys
6 in an amount yet to be determined, plus costs, expenses, and the maximum amount
7 of interest available under law.
8

9
10 **COUNT XXVI**
11 Unjust Enrichment

12 282. The allegations in all of the preceding paragraphs are incorporated by
13 reference as if fully set forth herein.
14

15 283. This is a claim for the recovery of monies by which Insys has been
16 unjustly enriched.
17

18 284. By directly or indirectly obtaining funds from the State of New York
19 to which it was not entitled, Insys has been unjustly enriched, and is liable to account
20 for and pay such amounts, or the proceeds therefrom, which are to be determined at
21 trial, to the State of New York, plus costs, expenses, and the maximum amount of
22 interest available under law.
23

24 **F. CLAIMS OF THE STATE OF NORTH CAROLINA**

25 **COUNT XXVII**
26 North Carolina False Claims Act
27 N.C.G.S. § 1-607(a)(1)
28

1 285. The allegations in all of the preceding paragraphs are incorporated by
2
3 reference as if fully set forth herein.

4 286. Through the acts described above, Insys violated the North Carolina
5 False Claims Act by knowingly, as defined in N.C.G.S. § 1-606(4), presenting or
6
7 causing to be presented a false or fraudulent claim for payment or approval.

8 287. Insys knowingly offered and paid kickbacks to potential prescribers to
9
10 induce them to prescribe Subsys for their patients, marketed Subsys for other than
11 FDA approved uses, encouraged prescribers to prescribe Subsys in situations where
12 it was not medically reasonable and necessary based on patients' medical conditions,
13 and misrepresented patients' medical diagnoses to obtain reimbursement for Subsys.
14
15 Insys offered and paid prescribers and other health care providers in violation of 42
16 U.S.C. § 1320a-7(b) and North Carolina law and regulations. As a result of
17
18 kickbacks paid by Insys, along with Insys's false and fraudulent statements,
19 misrepresentations, and omissions, providers submitted or caused to be submitted
20
21 false claims for payment or approval to the North Carolina Medicaid Program.

22 288. Insys's actions, including the offer and payment of kickbacks and the
23
24 false and fraudulent statements and representations made by Insys, were material to
25
26 the payment of claims submitted or caused to be submitted by Insys to the North
27
28 Carolina Medical Assistance Program.

1 289. Insys presented, or caused to be presented, false or fraudulent claims
2 with actual knowledge of their falsity, or with deliberate ignorance as to their truth
3 or falsity, or with reckless disregard of their truth or falsity.
4

5 290. As a result of the false or fraudulent claims Insys knowingly presented
6 or caused to be presented, Insys is liable to the State of North Carolina for civil
7 penalties of not less than \$5,500 and not more than \$11,000 for each violation, plus
8 three times the amount of actual damages that the State of North Carolina sustained
9 because of Insys's wrongful conduct.
10

11
12 **COUNT XXVIII**
13 North Carolina False Claims Act
14 N.C.G.S. § 1-607(a)(2)

15 291. The allegations in all of the preceding paragraphs are incorporated by
16 reference as if fully set forth herein.

17 292. Through the acts described above, Insys violated the North Carolina
18 False Claims Act by knowingly making, using or causing to be made or used, a false
19 record or statement material to a false or fraudulent claim.
20

21 293. Insys knowingly offered and paid kickbacks to potential prescribers to
22 induce them to prescribe Subsys for their patients, marketed Subsys for other than
23 FDA approved uses, encouraged prescribers to prescribe Subsys in situations where
24 it was not medically reasonable and necessary based on patients' medical conditions,
25 and misrepresented patients' medical diagnoses to obtain reimbursement for Subsys.
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1 Insys offered and paid prescribers and other health care providers in violation of 42
2 U.S.C. § 1320a-7(b) and North Carolina law and regulations. As a result of
3 kickbacks paid by Insys, along with Insys's false and fraudulent statements,
4 misrepresentations, and omissions, providers submitted or caused to be submitted
5 false claims for payment or approval to the North Carolina Medicaid Program.
6

7
8 294. Insys's actions, including the offer and payment of kickbacks and the
9 false and fraudulent statements and representations made by Insys, were material to
10 the payment of claims submitted or caused to be submitted by Insys to the North
11 Carolina Medicaid Program and the North Carolina Medicaid Program would not
12 have paid such claims had it known of such false and fraudulent records and
13 statements.
14

15
16 295. Insys made, used, or caused to be made or used, false records or
17 statements material to false or fraudulent claims with actual knowledge of their
18 falsity, with deliberate ignorance as to their truth or falsity, or with reckless disregard
19 as to their truth or falsity.
20

21 296. As a result of the false records or statements material to the false or
22 fraudulent claims Insys knowingly made, used, or caused to be made or used, Insys
23 is liable to the State of North Carolina for civil penalties of not less than \$5,500 and
24 not more than \$11,000 for each violation, plus three times the amount of actual
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28

1 damages that the State of North Carolina sustained because of Insys's wrongful
2 conduct.

3
4 **COUNT XXIX**

5 North Carolina False Claims Act
6 N.C.G.S. § 1-607(a)(3)

7 297. The allegations in all of the preceding paragraphs are incorporated by
8 reference as if fully set forth herein.

9 298. Through the acts described above, Insys violated the North Carolina
10 False Claims Act by conspiring with providers and others to knowingly present, or
11 cause to be presented, a false or fraudulent claim for payment to the State of North
12 Carolina.
13

14 299. Insys knowingly conspired with providers and others to offer and pay
15 kickbacks to induce potential prescribers to prescribe Subsys for their patients, to
16 market Subsys for other than FDA approved uses, to encourage prescribers to
17 prescribe Subsys in situations where it was not medically reasonable and necessary
18 based on patients' medical conditions, and to misrepresent patients' medical
19 diagnoses to obtain reimbursement for Subsys. Insys conspired with providers and
20 others to offer and pay prescribers and other health care providers in violation of 42
21 U.S.C. § 1320a-7(b) and North Carolina law and regulations. As a result of
22 kickbacks paid by Insys, along with Insys's false and fraudulent statements,
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1 misrepresentations, and omissions, providers submitted or caused to be submitted
2 false claims for payment or approval to the North Carolina Medicaid Program.

3 300. Insys knowingly conspired with providers and others to make, use, or
4 cause to be made or used, a false record or statement material to an obligation to pay
5 or transmit money or property to the State, or knowingly conspired to conceal or
6 knowingly and improperly avoid an obligation to pay or transmit money or property
7 to the State.
8

9 301. Insys's actions, including the offer and payment of kickbacks and the
10 false and fraudulent statements and representations made by Insys, were material to
11 the payment of claims submitted or caused to be submitted by Insys to the North
12 Carolina Medicaid Program and the North Carolina Medicaid Program would not
13 have paid such claims had it known of such false and fraudulent records and
14 statements.
15

16 302. Insys conspired with providers and others to present claims, or caused
17 claims to be presented, and to make, use, or cause to be made or used, records or
18 material statements with actual knowledge of their falsity, with deliberate ignorance
19 as to their truth or falsity, or with reckless disregard as to their truth or falsity.
20

21 303. Insys is liable to the State of North Carolina for civil penalties of not
22 less than \$5,500 and not more than \$11,000 for each violation, plus three times the
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1 amount of actual damages that the State of North Carolina sustained because of
2 Insys's wrongful conduct.

3
4 **COUNT XXX**

5 North Carolina False Claims Act
6 N.C.G.S. § 1-607(a)(7)

7 304. The allegations in all of the preceding paragraphs are incorporated by
8 reference as if fully set forth herein.

9 305. Through the acts described above, Insys violated the North Carolina
10 False Claims Act by knowingly making, using or causing to be made or used, a false
11 record or statement material to an obligation to pay or transmit money or property
12 to the State, or knowingly conceals or knowingly and improperly avoids or decreases
13 an obligation to pay or transmit money or property to the State. Insys knowingly
14 offered and paid kickbacks to potential prescribers to induce them to prescribe
15 Subsys for their patients, marketed Subsys for other than FDA approved uses,
16 encouraged prescribers to prescribe Subsys in situations where it was not medically
17 reasonable and necessary based on patients' medical conditions, and misrepresented
18 patients' medical diagnoses to obtain reimbursement for Subsys. Insys offered and
19 paid prescribers and other health care providers in violation of 42 U.S.C. § 1320a-
20 7(b), N.C.G.S. § 108A-63(g)-(h), and North Carolina law and regulations. As a
21 result of kickbacks paid by Insys, along with Insys's false and fraudulent statements,
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1 misrepresentations, and omissions, providers submitted or caused to be submitted
2 false claims for payment or approval to the North Carolina Medicaid Program.

3 306. Insys's actions, including the offer and payment of kickbacks and the
4 false and fraudulent statements and representations made by Insys, were material to
5 the payment of claims submitted or caused to be submitted by Insys to the North
6 Carolina Medicaid Program.
7

8 307. Insys made, used, or caused to be made or used, records or material
9 statements or concealed or improperly avoided or decreased payment obligations
10 with actual knowledge of their falsity, with deliberate ignorance as to their truth or
11 falsity, or with reckless disregard as to their truth or falsity.
12

13 308. Insys knowingly made, used, or caused to be made or used, false
14 records or statements material to an obligation to pay or transmit money or property
15 to the State or knowingly concealed or knowingly and improperly avoided or
16 decreased an obligation to pay or transmit money or property to the State.
17

18 309. As a result of the false or fraudulent claims Insys knowingly made,
19 used, or caused to be made or used, or Insys's knowing concealment or knowing and
20 improper avoidance of an obligation to pay or transmit money to the State, Insys is
21 liable to the State of North Carolina for civil penalties of not less than \$5,500 and
22 not more than \$11,000 for each violation, plus three times the amount of actual
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1 damages that the State of North Carolina sustained because of Insys's wrongful
2 conduct.

3
4 **COUNT XXXI**
5 Common Law Fraud

6 310. The allegations in all of the preceding paragraphs are incorporated by
7 reference as if fully set forth herein.

8 311. As a result of kickbacks paid by Insys, providers purchased, ordered,
9 recommended or arranged for the purchase or order of Subsys that was paid for in
10 whole or in part by the North Carolina Medicaid Program. Insys's willful false
11 statements, willful misrepresentations, and fraudulent scheme caused providers and
12 pharmacies in the State of North Carolina to submit claims to North Carolina
13 Medicaid for reimbursement based on false, fraudulent, and misleading information.
14 As a result, Insys caused false and fraudulent claims to be submitted to the North
15 Carolina Medicaid Program. Insys's conduct directly resulted in a significant
16 financial loss to the North Carolina Medicaid program.

17 312. Insys intentionally and knowingly made or caused fraudulent
18 statements to be made to the State of North Carolina.

19 313. Insys intended that the State of North Carolina rely upon these material
20 misrepresentations.

21 314. The State of North Carolina did, in fact, reasonably rely upon Insys's
22 fraudulent misrepresentations and suffered damages as a result of Insys's false

1 representations and the State of North Carolina's reasonable and actual reliance
2 thereon.

3
4 315. Insys caused North Carolina to sustain actual damages in an amount to
5 be determined at trial.

6
7 316. The State of North Carolina is entitled to recover from Insys the
8 repayment of any benefits or payments received as a result of Insys's false
9 representations, in an amount to be determined at trial.

10
11 **COUNT XXXII**

12 Payment Under Mistake of Fact

13
14 317. The allegations in all of the preceding paragraphs are incorporated by
15 reference as if fully set forth herein.

16
17 318. The above described false claims and false statements which Insys
18 submitted or caused to be submitted constituted misrepresentations of material fact.

19
20 319. Through its acts described above, Insys caused the State of North
21 Carolina to make payments by mistake to Insys and, as a result, the State of North
22 Carolina has suffered actual damages of at least \$4.8 million.

23
24 **COUNT XXXIII**

25 Unjust Enrichment

26
27 320. The allegations in all of the preceding paragraphs are incorporated by
28 reference as if fully set forth herein.

321. Insys received unjust enrichment when it:

1 (1) Received a measurable benefit conferred on it by the State of
2 North Carolina and/or the Medical Assistance Program;

3 (2) Consciously accepted the benefit conferred; and

4 (3) The benefit was not conferred officiously or gratuitously.
5

6 322. Insys obtained monies as a result of its violations of federal and state
7 law and Insys was not entitled to payments it received for the sale of Subsys. Insys
8 made materially false and fraudulent statements that caused the State of North
9 Carolina and/or the Medical Assistance Program to sustain large financial losses and
10 pay more in Medicaid payments for Subsys than it would otherwise have paid if
11 Insys made true and accurate statements regarding Subsys.
12

13 323. These materially false and fraudulent statements were reasonably
14 calculated to deceive North Carolina Medicaid Providers and cause them to submit
15 fraudulent Medicaid reimbursement claims to North Carolina's Medicaid Program.
16

17 324. The State of North Carolina and/or the Medical Assistance Program,
18 unaware of the falsity or fraudulent nature of the claims submitted by or caused to
19 be submitted by Insys, paid for claims that otherwise would not have been allowed.
20

21 325. By retaining monies that actually belonged to the State of North
22 Carolina, and/or otherwise receiving and retaining the benefit of North Carolina's
23 Medicaid Insys overpayments, Insys retained money that is the property of the State
24 of North Carolina to which Insys was not entitled.
25
26
27
28

1 326. As a direct and proximate result of Insys's actions, and as a direct and
2 proximate result of the overpayments made by the State of North Carolina and/or
3 the Medical Assistance Program, Insys realized the value of said overpayments for
4 itself, and retained the benefit of the same for itself, by selling far more Subsys in
5 North Carolina than they would have but-for Insys's fraudulent actions.
6

7 327. Insys has been unjustly enriched in the amount of at least \$4.8 million.
8
9 The State of North Carolina is entitled to the return of these monies.

10 **G. CLAIMS OF THE COMMONWEALTH OF VIRGINIA**

11 **COUNT XXXIV**

12 Virginia Fraud Against Taxpayers Act
13 Va. Code Ann. § 8.01-216.3(A)(1)

14 328. The allegations in all of the preceding paragraphs are incorporated by
15 reference as if fully set forth herein.
16

17 329. The Virginia Fraud Against Taxpayers Act ("VFATA") provides, in
18 pertinent part, that any person who:
19

20 (A)(1). Knowingly presents, or causes to be presented, a false or
21 fraudulent claim for payment or approval;

22 ***

23 shall be liable to the Commonwealth for a civil penalty of not less than
24 \$5,500 and not more than \$11,000, plus three times the amount of
25 damages sustained by the Commonwealth.
26
27
28

1 Va. Code Ann. § 8.01-216.3(A)(1).⁴⁴

2 330. As a result of kickbacks paid by Defendant Insys, providers purchased,
3 ordered, recommended or arranged for the purchase or order of Subsys that was paid
4 for in whole or in part by the Virginia Medicaid program, in violation of the federal
5 anti-kickback statute, 42 U.S.C. § 1320a-7b(b), and Virginia's anti-kickback statute,
6 Va. Code Ann. § 32.1-315.
7

8
9 331. The actions of Insys, including the offer and payment of kickbacks and
10 the false and fraudulent statements and representations made by Insys, were material
11 to the payment of claims submitted or caused to be submitted by Insys to the Virginia
12 Medicaid program.
13

14 332. The Virginia Medicaid program would not have paid such claims had
15 it known of Insys's false and fraudulent statements and omissions of fact.
16
17
18
19
20

21 ⁴⁴ In order to effectuate compliance with the Deficit Reduction Act of 2005, Pub. L. 109-171, tit.
22 VI, § 6031 (2006) (codified at 42 U.S.C. § 1396h), on or about March 30, 2018, the Virginia
23 General Assembly amended the penalty language in Va. Code Ann. § 8.01-216.3 to provide that
those who violate the VFATA:

24 shall be liable to the Commonwealth for a civil penalty of not less than \$10,957 and
25 not more than \$21,916, except that these lower and upper limits on liability shall
26 automatically be adjusted to equal the amounts allowed under the Federal False
27 Claims Act, 31 U.S.C. § 3729 et seq., as amended, as such penalties in the Federal
28 False Claims Act are adjusted for inflation by the Federal Civil Penalties Inflation
Adjustment Act of 1990, as amended (28 U.S.C. § 2461 Note, P.L. 101-410), plus
three times the amount of damages sustained by the Commonwealth.

334. By virtue of the acts alleged above, Insys knowingly presented, or caused to be presented, false or fraudulent claims to the Virginia Medicaid program in violation of Va. Code Ann. § 8.01-216.3(A)(1).

COUNT XXXV

336. The allegations in all of the preceding paragraphs are incorporated by reference as if fully set forth herein.

(A)(2). Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

shall be liable to the Commonwealth for a civil penalty of not less than \$5,500 and not more than \$11,000, plus three times the amount of damages sustained by the Commonwealth.

1 Va. Code Ann. § 8.01-216.3(A)(2).

2
3 338. As a result of kickbacks paid by Defendant Insys, providers purchased,
4 ordered, recommended or arranged for the purchase or order of Subsys that was paid
5 for in whole or in part by the Virginia Medicaid program, in violation of the federal
6 anti-kickback statute, 42 U.S.C. § 1320a-7b(b), and Virginia's anti-kickback statute,
7 Va. Code Ann. § 32.1-315.
8

9
10 339. The actions of Insys, including the offer and payment of kickbacks and
11 the false and fraudulent statements and representations made by Insys, were material
12 to the payment of claims submitted or caused to be submitted by Insys to Virginia
13 Medicaid, and the Virginia Medicaid program would not have paid such claims had
14 it known of Insys's false and fraudulent statements and omissions of fact.
15

16 340. Insys made, used, or caused to be made or used, false records or
17 statements material to false or fraudulent claims with actual knowledge of their
18 falsity, with deliberate ignorance as to their truth or falsity, or with reckless disregard
19 as to their truth or falsity.
20

21
22 341. By virtue of the acts alleged above, Insys knowingly made, used, or
23 caused to be made or used, false records or statements material to false or fraudulent
24 claims to the Virginia Medicaid program in violation of Va. Code Ann. § 8.01-
25 216.3(A)(2).
26

1 342. As a result of the false records or statements material to false or
2 fraudulent claims Insys knowingly made, used, or caused to be made or used, Insys
3 is liable to the Commonwealth of Virginia for civil penalties of not less than \$5,500
4 and not more than \$11,000 for each violation, plus three times the amount of actual
5 damages that the Commonwealth of Virginia sustained because of Insys's wrongful
6 conduct, as well as attorney fees and costs.
7
8

9 **COUNT XXXVI**
10 Virginia Fraud Against Taxpayers Act
11 Va. Code Ann. § 8.01-216.3(A)(3)

12 343. The allegations in all of the preceding paragraphs are incorporated by
13 reference as if fully set forth herein.

14 344. The VFATA provides, in pertinent part, that any person who:
15
16 (A)(3). Conspires to commit a violation of subdivision 1, 2, 4, 5, 6, or
17 7;

18 ***

19 shall be liable to the Commonwealth for a civil penalty of not less than
20 \$5,500 and not more than \$11,000, plus three times the amount of
21 damages sustained by the Commonwealth.

22 Va. Code Ann. § 8.01-216.3(A)(3).

23 345. As a result of kickbacks paid by Defendant Insys, providers purchased,
24 ordered, recommended or arranged for the purchase or order of Subsys that was paid
25 for in whole or in part by the Virginia Medicaid program, in violation of the federal
26

1 anti-kickback statute, 42 U.S.C. § 1320a-7b(b), and Virginia's anti-kickback statute,
2 Va. Code Ann. § 32.1-315.

3
4 346. The actions of Insys, including the offer and payment of kickbacks and
5 the false and fraudulent statements and representations made by Insys, were material
6 to the payment of claims submitted or caused to be submitted by Insys to Virginia
7 Medicaid, and the Virginia Medicaid program would not have paid such claims had
8 it known of Insys's false and fraudulent statements and omissions of fact..
9

10 347. Insys conspired with providers and others to present claims, or caused
11 claims to be presented, and to make, use, or cause to be made or used, records or
12 material statements with actual knowledge of their falsity, with deliberate ignorance
13 as to their truth or falsity, or with reckless disregard as to their truth or falsity.
14

15
16 348. By virtue of the acts alleged above, Insys conspired with providers and
17 others to knowingly present, or caused to be presented, false and fraudulent claims,
18 and to knowingly make, use, or cause to be made or used, false records or statements
19 material to false or fraudulent claims to the Virginia Medicaid program in violation
20 of Va. Code Ann. § 8.01-216.3(A)(3)
21

22 349. As a result of conspiring to commit violations of the VFATA as
23 described herein, Insys is liable to the Commonwealth of Virginia for civil penalties
24 of not less than \$5,500 and not more than \$11,000 for each violation, plus three times
25
26
27
28

1 the amount of actual damages that the Commonwealth of Virginia sustained because
2 of Insys's wrongful conduct, as well as attorney fees and costs.

3
4 **COUNT XXXVII**

5 Virginia Fraud Against Taxpayers Act
6 Va. Code Ann. § 8.01-216.3(A)(7)

7 350. The allegations in all of the preceding paragraphs are incorporated by
8 reference as if fully set forth herein.

9 351. The VFATA provides, in pertinent part, that any person who:

10 (A)(7). Knowingly makes, uses, or causes to be made or used, a false
11 record or statement material to an obligation to pay or transmit money
12 or property to the Commonwealth or knowingly conceals or knowingly
13 and improperly avoids or decreases an obligation to pay or transmit
14 money or property to the Commonwealth;

15 ***

16 shall be liable to the Commonwealth for a civil penalty of not less than
17 \$5,500 and not more than \$11,000, plus three times the amount of
18 damages sustained by the Commonwealth.

19 Va. Code Ann. § 8.01-216.3(A)(7).

20 352. As a result of kickbacks paid by Defendant Insys, providers purchased,
21 ordered, recommended or arranged for the purchase or order of Subsys that was paid
22 for in whole or in part by the Virginia Medicaid program, in violation of the federal
23 anti-kickback statute, 42 U.S.C. § 1320a-7b(b), and Virginia's anti-kickback statute,
24 Va. Code Ann. § 32.1-315.
25
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1 353. The actions of Insys, including the offer and payment of kickbacks and
2 the false and fraudulent statements and representations made by Insys, were material
3 to the payment of claims submitted or caused to be submitted by Insys to Virginia
4 Medicaid, and the Virginia Medicaid program would not have paid such claims had
5 it known of Insys's false and fraudulent statements and omissions of fact..
6

7 354. Insys made, used, or cause to be made or used, records or material
8 statements or concealed or improperly avoided or decreased payment obligations
9 with actual knowledge of their falsity, with deliberate ignorance as to their truth or
10 falsity, or with reckless disregard as to their truth or falsity.
11
12

13 355. By virtue of the acts alleged above, Insys knowingly made, used, or
14 causes to be made or used, false records or statements material to an obligation to
15 pay or transmit money or property to Virginia Medicaid or knowingly concealed or
16 knowingly and improperly avoided or decreased an obligation to pay or transmit
17 money or property to Virginia Medicaid.
18
19

20 356. As a result of the false records or statements material to false or
21 fraudulent claims Insys knowingly made, used, or caused to be made or used, or
22 Insys's knowing concealment or knowing and improper avoidance of an obligation
23 to pay or transmit money to the Virginia Medicaid program, Insys is liable to the
24 Commonwealth of Virginia for civil penalties of not less than \$5,500 and not more
25 than \$11,000 for each violation, plus three times the amount of actual damages that
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1 the Commonwealth of Virginia sustained because of Insys's wrongful conduct, as
2 well as attorney fees and costs.

3
4 **COUNT XXXVIII**
5 Virginia Fraud Statute
6 Va. Code Ann. § 32.1-312

7 357. The allegations in all of the preceding paragraphs are incorporated by
8 reference as if fully set forth herein.

9 358. The Virginia Fraud Statute provides, in pertinent part, that:

10 A. No person, agency or institution, but not including an individual
11 medical assistance recipient of health care, on behalf of himself or
12 others, whether under a contract or otherwise, shall obtain or attempt to
13 obtain benefits or payments where the Commonwealth directly or
14 indirectly provides any portion of the benefits or payments pursuant to
15 the Plan for Medical Assistance and any amendments thereto as
16 provided for in § 32.1-325, hereafter referred to as "medical assistance"
17 in a greater amount than that to which entitled by:

- 18 1. Knowingly and willfully making or causing to be made
19 any false statement or false representation of material fact;
20 2. Knowingly and willfully concealing or causing to be
21 concealed any material facts; or
22 3. Knowingly and willfully engaging in any fraudulent
23 scheme or device, including, but not limited to, submitting a
24 claim for services, drugs, supplies or equipment that were
25 unfurnished or were of a lower quality, or a substitution or
26 misrepresentation of items billed.

27 Va. Code Ann. § 32.1-312.

28 359. As a result of kickbacks paid by Insys, providers purchased, ordered,
recommended or arranged for the purchase or order of Subsys that was paid for in

1 whole or in part by the Virginia Medicaid program, in violation of the federal anti-
2 kickback statute, 42 U.S.C. § 1320a-7b(b), and Virginia's anti-kickback statute, Va.
3 Code Ann. § 32.1-315.
4

5 360. Insys's knowing and willful false statements, misrepresentations, and
6 fraudulent scheme caused providers and pharmacies in the Commonwealth of
7 Virginia to submit claims to Virginia Medicaid for reimbursement based on false,
8 fraudulent, and misleading information. As a result, Insys caused false and
9 fraudulent claims to be submitted to the Virginia Medicaid program and Insys's
10 conduct directly resulted in a significant financial loss to the Virginia Medicaid
11 program.
12

13
14 361. By virtue of the acts alleged above, Insys caused the Commonwealth of
15 Virginia to sustain actual damages in an amount to be determined at trial.
16

17 362. For each violation of Va. Code Ann. § 32.1-312, the Commonwealth of
18 Virginia is entitled to recover from Insys the repayment of any excess benefits or
19 payments received, plus interest, and civil penalties in an amount not to exceed three
20 times the amount of such excess benefits or payments.
21

22 **COUNT XXXIX**
23 **Common Law Fraud**

24 363. The allegations in all of the preceding paragraphs are incorporated by
25 reference as if fully set forth herein.
26
27
28

1 364. As a result of kickbacks paid by Insys, providers purchased, ordered,
2 recommended or arranged for the purchase or order of Subsys that was paid for in
3 whole or in part by the Virginia Medicaid program.
4

5 365. Insys's false statements, misrepresentations, and fraudulent scheme
6 caused providers and pharmacies in the Commonwealth of Virginia to submit claims
7 to Virginia Medicaid for reimbursement based on false, fraudulent, and misleading
8 information. As a result, Insys caused false and fraudulent claims to be submitted
9 to the Virginia Medicaid program and Insys's conduct directly resulted in a
10 significant financial loss to the Virginia Medicaid program.
11
12

13 366. Insys intentionally and knowingly made false representations of
14 material fact, or omissions of material fact, with the intent to mislead Virginia
15 Medicaid.
16

17 367. The Virginia Medicaid program was in fact misled, having reasonably
18 relied upon Insys's fraudulent misrepresentations, and suffered damages as a result
19 of Insys's false representations and the Virginia Medicaid program's reasonable and
20 actual reliance thereon.
21

22 368. By virtue of the acts alleged above, Insys caused the Commonwealth of
23 Virginia to sustain actual damages in an amount to be determined at trial.
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1 369. As a result of the above, the Commonwealth of Virginia is entitled to
2 recover from Insys the repayment of any benefits or payments received as a result
3 of Insys's false representations, in an amount to be determined at trial.
4

5 **COUNT XL**
6 Common Law
7 Unjust Enrichment

8 370. The allegations in all of the preceding paragraphs are incorporated by
9 reference as if fully set forth herein.

10 371. The Commonwealth of Virginia claims the recovery of all monies by
11 which Insys has been unjustly enriched, including profits earned by Insys because
12 of kickbacks and Insys's other unlawful and improper actions as described herein.
13

14 372. By obtaining monies as a result of its violations of federal and state law,
15 and its misrepresentations or omissions of material fact to the Virginia Medicaid
16 program, Insys was unjustly enriched. Insys is liable to account for and pay such
17 amounts, which are to be determined at trial, to the Commonwealth of Virginia.
18

19 373. By this claim, the Commonwealth of Virginia requests a full accounting
20 of all revenues (and interest thereon) and costs incurred by Insys for the marketing
21 and sale of Subsys, and disgorgement of all profits earned and/or imposition of a
22 constructive trust in favor of the Commonwealth of Virginia on those profits.
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1 374. The Commonwealth of Virginia is entitled to damages, in an amount to
2 be determined at trial, by reason of the funds unjustly obtained by Insys from the
3 Virginia Medicaid program.
4

5 375. The Commonwealth of Virginia seeks all relief it may be entitled to
6 under principles of equity for the harm it has suffered because of Insys's wrongful
7 conduct.
8

9 **WHEREFORE**, the Intervening States of California, Colorado, Indiana,
10 Minnesota, New York, North Carolina, and Virginia demand and pray for the
11 following relief:
12

13 (a) Entry of judgment in favor of the Intervening States and against
14 Defendant Insys;
15

16 (b) With respect to Counts I, II, III, IV, VIII, IX, X, XI, XII, XIII,
17 XIV, XIX, XXI, XXII, XXVII, XXVIII, XXIX, XXX, XXXIV,
18 XXXV, XXXVI, and XXXVII brought pursuant to the Intervening
19 States False Claims Acts, that judgment be entered against Defendant
20 Insys, in the amount to be determined at trial, trebled, plus civil
21 penalties for each violation in the range set by the False Claims Acts of
22 each Intervening state;
23
24

25 (c) With respect to Counts V, and VI brought pursuant to the State
26 of Colorado's False Claims Act, that judgment be entered in an amount
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1 to be determined at trial, doubled, plus civil penalties for each violation
2 in the range set by the False Claims Act of the state of Colorado;

3 (d) With respect to Counts XV-XVIII, for the State of Indiana's
4 Crime Victims Relief Act claims, all relief as set out in Ind. Code § 34-
5 24-3-1 including an amount not to exceed three times the actual
6 damages of the State as determined at trial, including, but not limited
7 to, the costs of the action, attorney's fees, expenses, and all other costs
8 of collection;
9

10 (e) With respect to Counts VII, XX, XXVI, XXXII, XXXIII, XL,
11 that judgment be entered against Defendant Insys in the amounts to be
12 determined at trial by which Defendant Insys was mistakenly paid and
13 unjustly and unlawfully enriched;
14

15 (f) With respect to Count XXIII for the State of New York's Social
16 Services Law, that judgment be entered against Defendant Insys for
17 treble damages, penalties, costs, and interest in the highest legal rate;
18

19 (g) With respect to Count XXIV for the State of New York's
20 Executive Law, that judgment be entered against Defendant Insys for
21 the economic injuries suffered by the State of New York;
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1 (h) With respect to Count XXV, that Defendant Insys pay the State
2 of New York restitution, plus costs, expenses, and the maximum
3 amount of interest available under the law;
4

5 (i) With respect to Count XXXI, for the State of North Carolina's
6 Common Law Fraud claim, that judgment be entered against Defendant
7 Insys in an amount to be determined at trial for North Carolina's loss
8 due to Defendant Insys's false representations;
9

10 (j) With respect to Count XXXVIII, for the Commonwealth of
11 Virginia's Fraud Statute claim, repayment of any excess benefits or
12 payments received, such amount to be determined at trial, plus interest
13 on the amount of the excess benefits or payments at the rate of 1.5
14 percent each month, and civil penalties in an amount not to exceed three
15 times the amount of such excess benefits or payments;
16

17 (k) With respect to Count XXXIX, for the Commonwealth of
18 Virginia's Common Law Fraud claim, that judgment be entered in an
19 amount not less than the Commonwealth of Virginia's loss due to
20 Defendant Insys's fraud, such amount to be determined at trial;
21

22 (l) That the Intervening States be afforded prejudgment and post-
23 judgment interest;
24
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1 (m) That the Intervening States be afforded costs, attorneys' fees
2 and/or expenses; and

3 (n) Such other relief as the Court may deem just and proper.
4

5 IX. DEMAND FOR JURY TRIAL

6 Pursuant to Federal Rule of Civil Procedure 38, the Intervening States hereby
7 demand a trial by jury in this action of all issues so triable.
8

9
10 Respectfully submitted,
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13 This the 8th day of August, 2018.
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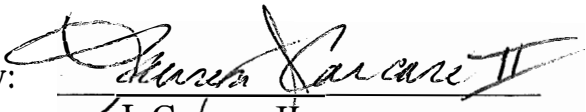
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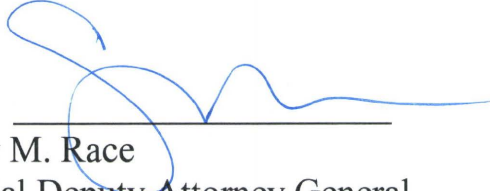
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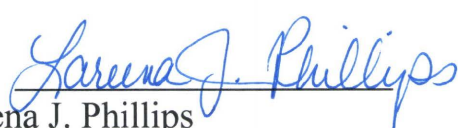
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PROOF OF SERVICE

Case Name: **U.S., ex rel. Maria Guzman v. INSYS Therapeutics, Inc., et al.**
No.: CV 13-5861 JLS (AJWx)

Case Name: **U.S., et al., ex rel. Jane Doe v. INSYS Therapeutics, Inc., et al.**
No. : CV 16-7937 JLS (AJWx)

I am over the age of 18 and not a party to the above-captioned actions. I am employed by the Medicaid Investigations Division of the North Carolina Attorney General's office. My business address is 5505 Creedmoor Rd., Suite 300, Raleigh, NC 27612.

On August 8, 2018, I served the foregoing COMPLAINT IN INTERVENTION OF THE INTERVENING STATES on each person or entity named below, by transmitting a true copy via electronic mail, pursuant to written consent under Federal Rule of Civil Procedures 5(b)(2)(E).

Date of e-mailing: August 8, 2018. Place of e-mailing: Raleigh, NC.

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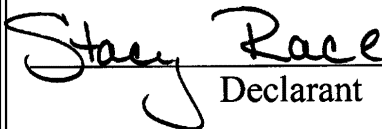
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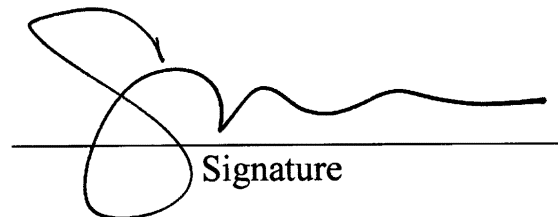
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I declare that I been admitted *pro hac vice* for the purpose of representing the
State of North Carolina in this matter.

I declare under penalty of perjury under the laws of the State of California the
foregoing is true and correct and that this declaration was executed on August 8,
2018, at Raleigh, North Carolina.


Declarant


Signature